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# **Research Guidelines**

Comprehensive Research Reference Manual

**Oakland University**



**Grants, Contracts and Sponsored Research  
Oakland University, 530 Wilson Hall  
Rochester, Michigan 48309  
[www.oakland.edu/research](http://www.oakland.edu/research)**



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- Chapter 9 Dr. Judette Haddad
- Chapter 10 Janet Schofding
- Chapter 11 Dr. Mary Duncan & Kathryn Wrench

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## Foreword

Since the historical ground breaking for the establishment of Oakland University in 1957, the institution has continued to evolve and expand its instructional, scholastic and creative works activities. From a satellite to a regional institution; from a comprehensive to a doctoral research-intensive university – Oakland's growth has been possible due to the quality of its education, the credentials of our faculty and the dedication of our staff. Although the university was a proud custodian of liberal arts education championing humanities, the arts, and languages in the fifties and sixties, the growth in recent years has also been assisted by the addition of strong components of professional schools to the university's roster. By all accounts, we have come of age as a mature institution with educational and research programs that are recognized nationally and internationally.

The Office of Grants, Contracts and Sponsored Research (GCSR) has taken a giant step in producing the first comprehensive research guide, or reference manual, to assist researchers, investigators, faculty and students alike, in pursuing their passion in research and engaging in projects that are within the scope of compliance of local, state or federal regulatory agencies. The document was produced by a team of committed GCSR staff members under the guidance of the Vice Provost for Research, Dr. T.C. Yih. It is hoped that this important resource will benefit our faculty researchers and colleagues in effectively carrying out their research plans.

Virinder K. Moudgil  
Provost & Senior Vice President for Academic Affairs

# Introduction

To further improve the research infrastructure and service to the research community at Oakland University (OU), the Office of Grants, Contracts & Sponsored Research (GCSR) has developed the **OU Research Guidelines – a Comprehensive Research Reference Manual**. This research handbook is a collection of campus wide research related guidelines and policies developed by different units. The Research Guidelines, along with the web version, will provide a quick reference for researchers looking for research related information.

It is with great pleasure that I offer you the opportunity to use this book when pursuing your research endeavors. As always, I encourage your feedback on this OU Research Guidelines. Upon receiving additional feedback from the campus, we will revise and update the Guidelines in a timely manner.

If you have any questions or would like to discuss any area of research, research compliance, regulatory compliance, or other research related issues, please do not hesitate to contact the GCSR office at [research@oakland.edu](mailto:research@oakland.edu).

T.C. Yih  
Vice Provost for Research

## Chapter 1: Research

### 1.1 Research

#### a. OMB Definition on Organized Research and Departmental Research

The Office of Management and Budget (OMB), Executive Office of the President of the U.S., has defined organized research (including sponsored research and university research) and departmental research in its OMB Circular A-21 (Section B.1).

*Organized research* means all research and development activities of an institution that are separately budgeted and accounted for. It includes:

- 1) Sponsored research means all research and development activities that are sponsored by Federal and non-Federal agencies and organizations. This term includes activities involving the training of individuals in research techniques (commonly called research training) where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function.
- 2) University research means all research and development activities that are separately budgeted and accounted for by the institution under an internal application of institutional funds. University research, for purposes of this document, shall be combined with sponsored research under the function of organized research.
- 3) Departmental research means research, development and scholarly activities that are not organized research and, consequently, are not separately budgeted and accounted for. Departmental research is not considered as a major function, but as a part of the instruction function of the institution.

OMB also explains that major functions of an institution refers to instruction, organized research, other sponsored activities and other institutional activities.

- 1) Instruction means the teaching and training activities of an institution. Except for research training, this term includes all teaching and training activities, whether they are offered for credits toward a degree or certificate or on a non-credit basis, and whether they are offered through regular academic departments or separate divisions, such as a summer school division or an extension division.
- 2) Sponsored instruction and training means specific instructional or training activity established by grant, contract, or cooperative agreement. For purposes of the cost principles, this activity may be considered a major function even though an institution's accounting treatment may include it in the instruction function.
- 3) Other sponsored activities mean programs and projects financed by Federal and non-Federal agencies and organizations which involve the performance of work other than instruction and organized research. Examples of such programs and projects are health service projects, and community service programs. However, when any of these activities are undertaken by the institution without outside support, they may be classified as other institutional activities.

## **b. NSF, DHHS, and FDA Definitions**

National Science Foundation (NSF) defines the term Research and Development (R&D):

- 1) Research is systematic study directed toward fuller knowledge or understanding of the subject studied. Research is classified as either basic or applied, according to the objectives of the investigator.
- 2) Development is systematic use of the knowledge or understanding gained from research, directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes.

The Department of Health and Human Services (DHHS) defines *research* (Code of Federal Regulations, 45 CFR 46.102.d) as "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." Some examples of research activities include, but are not limited to, clinical investigations involving human subjects, animal research, conducting surveys, quality standards development, bioavailability/bioequivalence (BA/BE) methods for complex drug substances and drug products, epidemiological research studies, methodological and regulatory research in support of critical path initiatives, new clinical trial designs, scientific computational strategies for combinatorial [Center for Drug Evaluation and Research MAPP 4112.8; 5/22/06].

The Food and Drug Administration (FDA) construes the term "science" broadly, as encompassing all of the disciplines and activities within the FDA that have a scientific basis, e.g., research. The term "scientific research" was taken to include both laboratory and non-laboratory investigation that addresses questions either of immediate applicability to present-day regulatory problems, questions that can be expected to arise in the near-term, and fundamental studies in areas of contemporary biomedical research that can reasonably be anticipated to affect FDA review and regulatory responsibilities over the longer-term, but foreseeable, future (an example of the last category might be research into candidate recombinant vaccines or biological response modifiers under development for commercial application). Under this definition, "scientific research" would exclude routine laboratory or non-laboratory testing and analysis using established methodologies, but would include the development of new analytical approaches and methodologies.

## **c. Other Definitions**

Merriam-Webster Online Dictionary ([www.merriam-webster.com/dictionary/research](http://www.merriam-webster.com/dictionary/research)) defines *research* as 1) careful or diligent search, 2) studious inquiry or examination; especially investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws, or 3) the collecting of information about a particular subject.

*Scientific research* relies on the application of the scientific method, a harnessing of curiosity. This research provides scientific information and theories for the explanation of the nature and the properties of the world around us. It makes practical applications possible. Scientific research can be subdivided into different classifications according to their academic and application disciplines. For instance, *Business Research* is the examination of statistics and

other information regarding past, present, and future trends or performance that enables analysts to recommend to investors which stocks to buy or sell in order to maximize their return and minimize their risk. It may be used either in the top-down approach (where the investor evaluates a market, then an industry, and finally a specific company) or the bottom-up approach (where the investor selects a company and confirms his or her findings by evaluating the company's sector and then its market). Careful research is likely to help investors find the best deals, in particular value shares or growth equities.

## **1.2 Medical Research**

The *Translational Research* Working Group (TRWG) of the National Cancer Institute (NCI), National Institute of Health (NIH), defines Translational Research in the following way: "Translational research transforms scientific discoveries arising from laboratory, clinical, or population studies into clinical applications to reduce cancer incidence, morbidity, and mortality."

NIH Clinical and Translational Science Awards (CTSA) explains that translational science is the link between the two disciplines of basic (i.e., bench) research and clinical (i.e., bedside) research. It is about translating discoveries that scientists have made in the lab to develop real treatments that help patients. Translational science can also move in the other direction, when observations made at the patient's bedside stimulate new areas to explore in the lab.

### **a. Clinical Research**

The term "clinical" is derived from the Greek *klinikos*, meaning 1) of a bed, or 2) a physician who attends bedridden patients. The term "*clinical research*" is used in a less strict sense to mean research involving human subjects that is designed either to enhance the professional capabilities of individual physicians or to contribute to the fund of knowledge in those sciences that are traditionally considered basic in the medical school setting, e.g., biochemistry, physiology, pathology, pharmacology, epidemiology, and cognate behavioral sciences [Robert J. Levine, *Ethics & Regulation of Clinical research*; 1988].

NIH ([http://grants.nih.gov/grants/funding/women\\_min/training/sld007.htm](http://grants.nih.gov/grants/funding/women_min/training/sld007.htm)) defines *clinical research* as patient-oriented research that conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: 1) mechanisms of human disease, 2) therapeutic interventions, 3) clinical trials, and 4) development of new technologies.

NIH Clinical and Translational Science Awards (CTSA) further states that *clinical research* involves human subjects who volunteer to take part in scientific studies. Clinical research happens in hospitals, doctors' offices and communities. It includes trials that test new treatments and therapies as well as observational studies that help physicians see how disease changes over time and whether medications, lifestyle adjustments or other interventions affect it. Clinical research also involves taking proven research and finding ways to implement it to improve care.

### **b. Experimental Research**

*Experimental Research* is an attempt by the researcher to maintain control over all factors that may affect the result of an experiment. In doing this, the researcher attempts to determine or

predict what may occur [James P. Key, *Research Design in Occupational Education*; 1997]. In many cases, animals are used in different studies.

The most common applications of these designs in marketing research and experimental economics are test markets and purchase labs. The techniques are commonly used in other social sciences including sociology and psychology.

### **c. Bench Research**

NIH defines *bench research* that happens in laboratories and is focused on exploring the most basic functions of living systems, from humans down to single cell organisms. It may focus on a particular cellular substance or function, or a system in the body, and often uses model systems like human or animal cells, simple organisms like fruit flies or yeast, or higher animals like mice and rats.

Clinical research entails assisting doctors, nurses, and staff with patients enrolled in patient-focused studies whereas *bench research* entails working at a lab bench with test tubes, pipettes, gels, cells, and microbes.

Studies involving patients pose special methodological challenges that are not encountered in laboratory *bench research*. In bench research, the subjects of the experiment are selected to ensure that they are virtually identical. In clinical research, by contrast, the populations under study, even in studies involving identical twins, are never truly identical. Whereas in bench research experiments are conducted in such a manner that everything other than the experimental maneuver is applied to the control group, many aspects of clinical research studies cannot be controlled. Moreover, there are fewer constraints on how the results from bench studies can be assessed (i.e., isolation of cellular material, euthanasia of animals, *ex vivo* studies) [Careers in Clinical Research: Obstacles and Opportunities, Institute of Medicine, National Academy of Sciences; 1990].

Most nurses are well-acquainted with clinical research, in which investigators study how a new drug, device, or treatment affects patients. Bench research, however, may be less familiar. Unlike clinical research, bench research is generally performed in a laboratory and focuses on understanding the cellular and molecular mechanisms that underlie disease. While some bench research studies are conducted on single cells, a group of cells in culture, or tissue samples, other studies use animal models to examine how a particular gene or cellular mechanism relates to physiological or pathological systems. Although the settings and techniques associated with clinical research and biomedical bench research differ, the two fields share a common goal: finding new, more effective ways to combat disease.

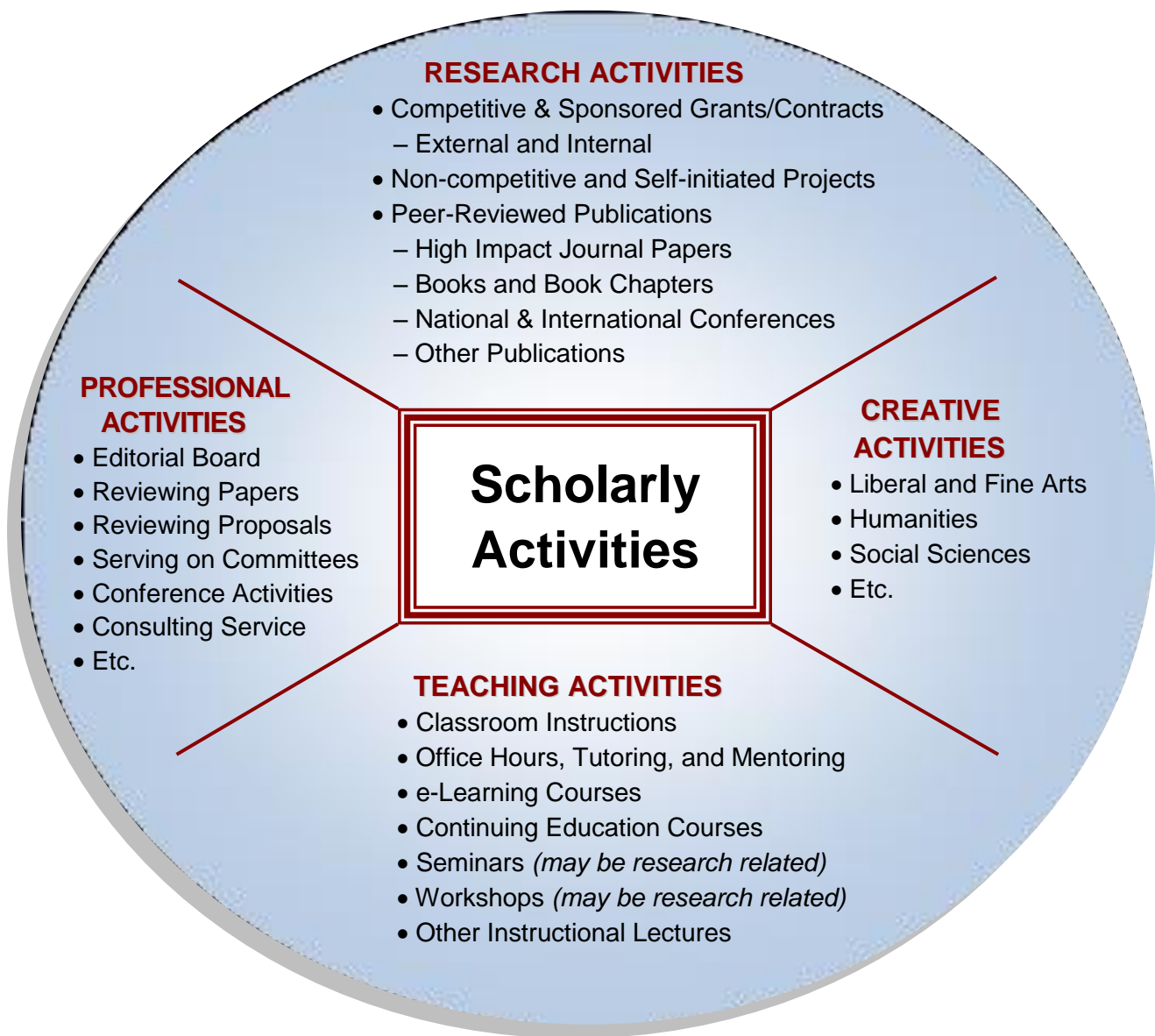
## **1.3 Scholarly Activities**

The term "*scholarly activity*" can be viewed narrowly or broadly; it can vary from program to program, or even between faculty members. Research extensive organizations have defined scholarly activity more narrowly, focusing only on competitive funded grants and peer-reviewed publications. Empirical research has shown that increased productivity is associated with the presence of human resources to support research and protected research time. Others have noted benefits from fellowship programs, requirements for scholarly work, strategic planning for research, or increased director support for scholarship [J. Hinojosa, K.L. Bene, C. Hickey, and K. Marvel, *Scholarly Activities of Family Medicine Faculty: Results of a National Survey*, Med Education Online; 2006]. Because of the disproportionate funding opportunity in different



research fields, many universities (e.g., Texas A&M University, Southeastern Louisiana University) have established competitive Scholarly and Creative (S&C) programs to promote faculty and student creative and scholarly activities. These awards will support scholarly and creative activities primarily in the humanities, arts, social sciences, and other disciplines in which external funding are typically limited or unavailable.

The broad definition of academic *scholarly activity* may be divided into the following categories: peer-reviewed journal articles, abstracts, chapters and books, conference publications and presentations, research grants and projects, teaching, other creative works, and other activities. Other scholarly or professional activities may include service to professional societies and committees, serving on an editorial board, reviewing papers and proposals, consulting service,



keynote and plenary addresses, research forums, etc. [Earl J. Reisdorff, Director of Medical Education, Ingham Regional Medical Center, Michigan State University Emergency Medicine Residency; Scholarly Activity: A Personal Odyssey, Navigating the Academic Waters; 2004] [The Board of Ethics of American Speech-Language-Hearing Association] [Seton Hall University; The Boonshoft School of Medicine of Wright State University; Carolinas Medical Center; Avondale College].

Research and scholarly activities are often considered hallmarks of the establishment of a true profession. These activities validate professional practice standards and promote advancement of knowledge in the field. In academia, research is often an expectation of faculty and may be the major determinant in tenure and promotion decisions. Clinical laboratory science (CLS) faculty therefore may be expected to engage in research and scholarly activities essential to the profession and to contribute to the research mission of the university [Kathy V. Waller, Diane Wyatt, and Karen R. Karni, Scholarly Activities among Clinical Laboratory Science Faculty, Clinical Laboratory Science; 1999].

#### 1.4 Search for Research Opportunities

Oakland University (OU) is currently supporting four search tools – **GRANTS.GOV**, **COS Funding Opportunities**, **GENIUS**, and **SPIN** – for researchers to search for grant opportunities. In particular, GENIUS will provide **automatic emails** with a list of potential grant opportunities specific to your search keywords. Instructions for using these search tools are listed below.

##### a. **GRANTS.GOV**

Grants.gov is a source to **FIND** and **APPLY** for federal government grants. The U.S. Department of Health and Human Services is the managing partner for Grants.gov, which is a central storehouse for information on over 1,000 grant programs and provides access to approximately \$500 billion in annual awards. To search in Grants.gov:

- 1) Go to the OU research webpage: <http://www2.oakland.edu/research>
- 2) On the left, click on: Faculty Funding Opportunities
- 3) Click on: External Grants
- 4) Click on: GRANTS.GOV
- 5) You can then conduct a basic or advanced search, or search by category or agency.

##### b. **GENIUS**

**GENIUS** (The Global Expertise Network for Industry, Universities, and Scholars) is a web-based database containing profiles of scholars and researchers at leading universities and research institutions throughout the world. As a searchable international registry of institutional expertise, GENIUS promotes industry and institutional collaboration. The database can be mined based on 1) free-text searches of full profiles, 2) keywords (as selected from the SPIN Keyword Thesaurus), 3) research interests (free-text search based on abstracts entered by investigators), and 4) institution, state, or country. To use the GENIUS database:

- 1) Go to the OU research webpage: <http://www2.oakland.edu/research>

- 2) On the left, click on: Faculty Funding Opportunities
- 3) Click on: Info Ed SPIN & GENIUS
- 4) Scroll down and click on: Link to GENIUS
- 5) Click on: Create a Profile
- 6) Click on: Please Pick an Institution (choose Oakland University)
- 7) Then just fill out the information and click: Submit

Once you have created your Username and Password, you will be taken to the Profile Summary Page.

- 1) Click on Keywords and choose keywords to search for grants in your areas of interest
- 2) Click on the link to a topic (on the left), and you will get keywords for that topic appear in the box on the right
- 3) Click on Select/Save Changes to add them to your profile
- 4) You will receive AUTOMATIC eMAILS with a list of grants based on the keywords for your topics

## **Chapter 2: Offices, Committees and Panels that Support Research**

**Oakland University's Research and Scholarship Mission Statement:** OU assumes an obligation to advance knowledge through the research and scholarship of its faculty and students. The university's research and scholarship mission takes expression in a variety of forms ranging from basic studies on the nature of things to applied research directed at particular problems to contributions to literature and the arts. The university provides internal financial support for research and scholarship and pursues external funding sources. In addition to their intrinsic value, research and scholarship reinforce the instructional mission of the university. Wherever possible, students are involved in research projects, and the results of research and scholarship are integrated into related courses of instruction.

In carrying out its research and scholarship mission, the university seeks to be responsive to the needs of Michigan, particularly of the populous southeastern sector. Application of research and scholarship to problems and concerns of the state's business and industry and to its scientific, educational, governmental and health and human-service agencies serves to reinforce the public service role of the university.

### **2.1 Committees, Councils and Governing Boards**

#### **a. Board of Trustees**

OU is governed by an eight-member Board of Trustees appointed by the governor to serve eight-year terms. The board provides general supervision of the university, including control and direction of all expenditures from the institution's funds. The board also appoints the university president as well as the secretary to the board and treasurer.

#### **b. President's Council**

OU President Gary Russi is serving as chair of the President's Council for the state universities of Michigan for the 2006-08 term and also served for the 2004-06 term. The Lansing-based Presidents Council is a nonprofit higher education association serving Michigan's 15 state universities. The primary mission of the Presidents Council is to advocate higher education as a public good and to promote its collective value in serving the public interest and the state of Michigan.

#### **c. The Senate**

The Senate is an all-university governance body whose membership includes administrative officers, students and faculty members elected for two year terms to represent academic units. The Vice President for Academic Affairs is the Senate's presiding officer. The Senate recommends new degree programs to the president and the board and must approve the constitutions of colleges and schools. It determines academic policies and provides opportunity for public deliberation on issues of importance to the university.

#### **d. Deans' Council**

Comprised of the Deans from the academic units and Kresge Library, and chaired by the Provost, the Deans' Council meets to consider policies and planning processes vital to the academic units. Working directly with senior academic leaders, the Provost seeks to advance the central mission of the university to ensure the quality of education and research at OU.

**e. Academic Council**

The Academic Council consists of senior administrators in the Division of Academic Affairs. The Council considers new and revised administrative policies and procedures, organizational and planning goals, and strategic issues affecting Academic Affairs.

**f. Academic Affairs Administrative Operations Group**

The Academic Affairs Administrative Operations Group meets to discuss academic employment and budget administration in the division. Participants include representatives from the Provost's Office, the Schools and Colleges of Academic Affairs, Budget, Registrar, Grants, Contracts & Sponsored Research, Kresge Library, Undergraduate Education, University Technology Services, E-learning & Instructional Support and Classroom Support & Instructional Technical Services.

**g. Administrative Council**

The Administrative Council is advisory to the university administration. It is chaired by the Vice President for Finance and Administration. All Administrative Council activities are coordinated by the Vice President for Finance and Administration, including reporting for the Council to the President and the Cabinet.

A single representative from each of the schools, the college, and divisions is appointed by the appropriate dean or vice president. The representative is in a position to speak for the unit on most administrative matters, and commits to bringing information back to the unit, as appropriate. Membership also includes senior leadership from major administrative units on campus.

The Administrative Council is charged with the responsibility to review and make recommendations regarding administrative policies and procedures affecting the University as a whole, but this responsibility does not extend to the internal affairs of the college, schools, divisions or other units of the University. The following are the specific functions of the Administrative Council:

- 1) To recommend policy on administrative matters; This includes the development of and/or advice on administrative policies, practices and procedures. It may also include internal operating procedures of individual administrative units that wish to seek input from the Council.
- 2) To assist the college, schools, divisions and other units of the University in the implementation of established administrative policies and procedures;
- 3) To recommend the need for new administrative policies or revisions in existing administrative policies; and
- 4) To assist in the development and implementation of a professional development program for the University administrative staff.

**h. University Research Committee (URC)**

The URC is comprised of ten faculty members, including two faculty representatives appointed by the Graduate Council. Membership also includes the Vice Provost for Research as an ex-officio and non-voting member. The charge of the Committee is “to encourage and promote scholarship, advanced studies, and research among students and the tenured and tenure-track faculty of Oakland University”. The URC’s responsibilities include, in particular, the evaluation of applications for intramural URC research funds and the allocation of these funds. More generally, they include protection and development of practices and policies conducive to URC funded scholarly activity. Scholarship is interpreted broadly and, in particular, includes creative endeavors.

The URC meets throughout the academic year to provide an uninterrupted flow of service to faculty and students. With the exception of URC members, students and the tenured and tenure-track faculty members at OU are invited to apply for research support under the categories and conditions outlined in these guidelines. Faculty funded under URC programs must have an active employment contract at the time of the application and during the period of completing his/her research project. Students funded by the URC must be enrolled at OU at the time of the application and during the period of completing his/her research project. All URC funded projects for faculty and students are expected to be performed on-campus. Any off-campus research activities must be clearly explained in the proposal and approved by the URC and committee Chair before starting the project. Requests for clarification of these guidelines or eligibility requirements may be obtained from the Chair of the URC.

## **2.2 Office of Grants, Contracts and Sponsored Research**

The Grants, Contracts and Sponsored Research Office (GCSR) manages the administrative processes related to OU’s internal and external sponsored research, research compliance, management of the animal facility, intellectual property and technology transfer. GCSR is responsible for establishing and promoting organizational policies that enhance research.

### **a. Office of Research Administration Home Page**

[www2.oakland.edu/research/research\\_new/pages/](http://www2.oakland.edu/research/research_new/pages/)

The Vice Provost for Research is the senior administrative official of the Office of Grants, Contracts and Sponsored Research.

### **RESPONSIBILITIES**

The mission of the GCSR is to provide high quality service and effective administrative expertise to the university research community.

GCSR reviews proposals and negotiates awards for educational projects and scholarly research undertaken by members of the University faculty. The office assures compliance with all applicable sponsor regulations, regulatory bodies, and University policies.

GCSR notifies and updates the university community about funding opportunities and sponsor policies and procedures.

GCSR facilitates proposal development through a variety of other pre-award and post award services, including conducting educational workshops.

GCSR staff assists faculty with the preparation of budgets and renders support and advice during the entire project period.

GCSR assures compliance in the safe and ethical conduct of research.

GCSR establishes and maintains accounts and records, seeks reimbursement for expenses from sponsors, fulfills administrative reporting requirements, and monitors sponsored projects for compliance with sponsor terms and conditions, university policies and Federal regulations.

GCSR responds to audit inquiries and coordinates site visits of sponsored programs.

**b. Research and Regulatory Compliance Committees**

Research conducted at OU is safe and ethical. To maintain this standard and to comply with federal as well as State of Michigan regulations and laws, the university has instituted the following regulatory committees:

- 1) Institutional Animal Care and Use Committee (IACUC)
- 2) Institutional Biosafety Committee (IBC)
- 3) Institutional Review Board (IRB)
- 4) Radiation Safety Committee (RSC)
- 5) Conflict of Interest Review Committee (COIRC)
- 6) Export Control Compliance Committee

Each committee has established operating guidelines and maintains a program to ensure compliance with applicable federal and state laws that provide protection against research risk in the following domains:

- 1) Animal care and use
- 2) Biosafety
- 3) Conflict of interest
- 4) Human participants
- 5) Radiation safety
- 6) Export Control Regulations

In addition to the regulatory committees, the university has established a Laboratory Safety Committee for assistance in identifying and minimizing laboratory hazards not specifically addressed by the regulatory committees. General laboratory safety also is the responsibility of Oakland's Office of Environmental Health and Safety (EH&S). This office is responsible for university compliance with federal, state and local health, safety and environmental regulations

(primarily OSHA and EPA). It provides instruction in laboratory safety to support this effort. Researchers using hazardous materials or procedures are required to participate in environmental health and safety programs. Information about EH&S is available at <http://www.oakland.edu/ehs/>.

Researchers and course directors, who are planning to conduct work in a domain covered by one or more of the regulatory committees, must make formal application to the appropriate committee(s) and agree to conform to the established program(s) before the activity begins. Disregard for the guidelines and programs established by these regulatory committees may result in the suspension or revocation of privileges. Full access to information for each of the committees is available in the regulatory environment section of Oakland's research web site, [www.oakland.edu/research](http://www.oakland.edu/research).

### **c. Regulatory Compliance Requirements**

All research and instructional activities conducted at OU using materials owned by the university, or involving OU employees or students, must be submitted for consideration and approval by appropriate regulatory compliance committees if it involves:

- 1) Human subjects
- 2) Vertebrate animals
- 3) Materials of human origin, including fluids potentially contaminated with human blood
- 4) Recombinant DNA or potentially infectious materials such as cultured human cell lines, plant or animal retroviruses, parasites or bacteria
- 5) Radioactive materials or equipment producing ionizing radiation
- 6) Chemicals presenting reproductive, high acute or high chronic toxicity (including mutagens, teratogens and carcinogens) or that are flammable, reactive or corrosive
- 7) Hazardous chemical waste
- 8) Conflict of interest
- 9) Export control regulated areas or research involving restrictions on data access or publication rights.



## **Chapter 3: Academic Policies that Relate to Research**

### **3.1 Principles Concerning Research**

#### **a. Institutional Responsibility to Maintain Integrity in Research**

The university also has a significant history of conducting research and scholarly activity aimed at enhancing human life and the human condition. The faculty, staff, students and administration of Oakland University (OU) are obligated to maintain the highest possible standards of integrity in all research and scholarly activity. Given these principles and continuing tradition, the following guidelines govern the conduct of scholarly activity, as well as the acceptance of research grants, contracts, or agreements by the university and the subsequent responsible performance of the work supported whether funded through internal or external sources.

The university adheres to the principle that all research will be conducted in conformity with appropriate governmental regulations, as well as terms and conditions of sponsoring organizations, where applicable. Research conducted at the university should not expose investigators, students, associates, technicians, subjects or respondents to unreasonable risks to their health, general well-being, or privacy. All research should conform to professional standards of rigor and conduct. As in any complex organization, the rights, privileges and responsibilities of individual members cannot be completely documented. In addition to the general obligations outlined above, there are special constituency roles, defined in the following sections.

#### **b. Responsibility of Researchers and Supporting Staff**

All faculty members have a fundamental obligation to consider carefully the qualifications of students and staff to engage in research and to safeguard adequately the rights, safety, and well-being of any human or animal subjects and other members of the university community. In instances of sponsored research, responsibility for ensuring compliance with requirements of governmental entities or sponsors is first and foremost that of the project director. Faculty members should not initiate any research activities without obtaining the relevant regulatory compliance approval(s) and ensuring that all personnel working on the project have obtained appropriate training. Faculty members and project directors are responsible to be knowledgeable about government, university, and sponsor regulations pertinent to work carried out within their departments and to ensure adherence to these requirements by faculty, staff, and students.

The responsibility for appropriate research conduct also pertains to other members of the department, departmental chair, academic dean, and other administrators. This is most obvious in cases of sponsored research, since, departmental, collegiate and administrative approvals that ensure adequate resources and oversight are required before proposals may be submitted to sponsors.

The Vice Provost for Research has primary responsibility for the coordination of research compliance oversight through various offices and committees throughout the institution.

OU is committed to maintain an environment of ethical, safe, and responsible research conduct that promotes the discovery of knowledge. To that end, Oakland provides a supporting structure of governance and resources meet that commitment. In all circumstances and at all

times, faculty, students, staff, and others involved with research, instruction, or public service are expected to maintain professional integrity and to act within the framework of regulatory compliance.

### **3.2 Eligibility to Serve as the Principal Investigator at OU**

#### Definition of the Principal Investigator

The principal investigator (alternatively project director) is the person responsible for the administrative and programmatic aspects of the proposed project. The principal investigator must possess independent technical competence and other related capabilities to lead the sponsored project as proposed and accepted by the sponsoring organization. Although it is recognized that the principal investigator conceptualizes the project, creates a proposal, and is responsible for project execution; it is the institutional responsibility to act as a fiduciary of funding entrusted for the conduct of research or other activity.

#### Duties of the Principal Investigator

The principal investigator has direct accountability to the university and sponsoring organization to lead efforts towards meeting the goal(s) of the project as proposed and to act accord with professional standards of conduct, including compliance with all regulatory requirements, the ethical and safe conduct of research, and to monitor that funds are expended in accordance with any restrictions whether imposed by the university or sponsoring organization. The principal investigator has primary responsibility of scholarly integrity of the project. As a mature professional in the field of research, the principal investigator is expected to act as a mentor to less senior colleagues and to maintain a high standard of performance within the area of scholarly expertise.

#### Eligibility to Serve as the Principal Investigator

Generally, the principal investigator must have an appointment with the university as a tenure track faculty member. The principal investigator must have the approval of the dean and departmental chair within the scholarly area. All tenure track faculty may serve as principal investigators, non-tenure track professionals may serve as co-investigators on research projects or principal investigators on projects involving public service, instruction, or other non-research activity. Only persons holding an academic title of professor, associate professor, assistant professor, and instructor are considered tenure track faculty. Titles of senior research scientist, associate research scientist, assistant research scientist, adjunct faculty, and special lecturers are not eligible to serve as principal investigator on research projects at OU.

Circumstances may permit the designation of a principal investigator who is appointed as a Research Faculty Non-Tenure Track Faculty member. These circumstances are evaluated in light of the research being conducted, sponsor guidelines, and the researcher's association with OU as well as the affiliated hospital. An employee of OU is bound to act in accord with an employment contract and provided support within the administrative framework of their respective unit. Non-university employees do not have a relationship with the university that assures the necessary support and accountability for the execution of the project.

Post-doctoral scholars and research fellows are considered to be in training and are not regarded as independent. However, some sponsored programs are directed specifically to the

support of post-doctoral candidates and/or graduate students (e.g., fellowships, traineeships, grant-in-aid programs). The post-doctoral candidate or graduate student may be designated as the principal participant in proposals for such projects under the professional guidance of a faculty member who would serve as the principal investigator.

### Exceptions to Policy

Any request for exception of this policy requires a written document from the dean or director and departmental chair supporting the principal investigator designation and explaining why the exception is necessary. The document must accompany each proposal to which the exception applies. Ultimate fiscal and program responsibility for a project may revert to the dean, director, or departmental chair office if the designated principal investigator is unable to complete the project for any reason.

### **3.3 Research Integrity and Research Misconduct**

The responsible conduct of research is fundamental to the integrity of research results, public health, safety, and the welfare of society. A uniform policy has been established to provide guidance on the handling of misconduct allegations because misconduct is expected to rarely occur. University Officials will often not have experience in the inquiry and investigation of misconduct, due to the serious nature of an allegation of misconduct it is important that the process of inquiry and investigation is performed in a manner that is timely, impartial, confidential, and compliant with regulatory requirements.

In the investigation of misconduct allegations, OU will comply with the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93, which outlines the responsibilities of awardee and applicant institutions for dealing with and reporting possible misconduct in science. Allegations of misconduct which contain credible substance will be received and acted upon by a responsible institutional official in a manner that preserves confidentiality and observes an administrative order of due process in inquiry and investigation.

It is a fundamental responsibility of the faculty, staff, students, and administration of OU to maintain the highest possible standards of integrity in all research and scholarly activity. It is the shared responsibility of all members of our academic community to assure that misconduct or fraud in academic endeavors is dealt with effectively, and that the reputation of the University for High Standards of scholarly integrity is not tarnished. All members of our academic community have an obligation to report potential misconduct and to cooperate in the investigation of such behavior.

#### **a. Definitions**

- 1) Allegation. A disclosure made through any means of communication. The disclosure may be oral or written, but must contain substantive details of the observation and any supporting documentation.
- 2) Burden of Proof. OU has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent's failure to provide research records does not exonerate the respondent from a finding of research misconduct where the preponderance of evidence indicates that the respondent had the ability to preserve,

maintain or produce research records. Failure to produce research records is a significant departure from accepted conduct in the research community.

- 3) Claimant. A person who, in good faith, makes an allegation of research misconduct or impropriety.
- 4) Confidentiality. Abuse of confidentiality shall mean use of ideas or data gained from access to privileged information through activities such as, but not limited to, critical or editorial review of colleague manuscripts or peer review of research proposals for granting agencies or internal university committees established to support to regulate research.
- 5) Evidence. Any tangible item offered or obtained that tends to prove or disprove the alleged action.
- 6) Fabrication is making up data or results and recording or reporting them. Fabrication of research data include such conduct as, but not limited to:
  - reporting experiments, measurements or statistical analyses never performed,
  - deliberate and intentional manipulation of data or other supposed results of research in order to achieve a desired result,
- 7) Falsification is manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Falsification of research data include such conduct as, but not limited to:
  - deliberate and intentional manipulation of other source material (e.g., biographical data, manuscripts, documents, cited published material), and
  - deliberate and intentional selective reporting, including suppression of conflicting and unwanted data.
- 8) Inquiry. A preliminary review that begins with accepting the original allegation and includes all activity prior to the determination that an investigation is warranted or that research misconduct has not occurred prior to an investigation.
- 9) Investigation. The formal proceeding of leading to a decision of research misconduct or exoneration from an allegation of misconduct.
- 10) Plagiarism. OU subscribes to the definition of plagiarism developed by the American Association of University Professors, which is the "...taking over the ideas, methods, or written words of another (whether published or unpublished), without acknowledgment, and with the intention that they be taken as the work of the deceiver..." (American Association of University Professors, 1990, "Statement on Plagiarism.")
- 11) Research Misconduct: Misconduct is defined as fabrication and/or falsification of research data, and/or plagiarism in proposing, performing, or reviewing research, or in reporting research results that does not involve honest error or differences of opinion.
- 12) Research Impropriety: Impropriety is defined any ethical lapse involving or occurring in connection with research other than research misconduct and include conduct of, but not limited to:
  - abuse of confidentiality;

- deliberate misrepresentation of qualifications, experience, affiliations, or research accomplishments to obtain external funding or professional advancement;
  - material failure to comply with requirements affecting specific aspects of research sponsored by federal or other agencies, or to comply with university requirements governing the conduct of research that may involve use of funds, care of animals, human subjects, investigational drugs, recombinant products, new devices, or radioactive, biologic, or chemical materials;
  - retaliation or the threat of retaliation of any kind against any person who has, in good faith, provided information about suspected or alleged misconduct; or
  - Impropriety may involve matters not defined within this document. The description of impropriety contained within this policy is not intended to represent an exclusive, comprehensive, or exhaustive list of acts considered improprieties.
- 13) Respondent. Person who is the subject of an allegation, inquiry, or investigation of research misconduct or impropriety.
  - 14) Requirements. University or sponsor requirements which affect research include, but are not limited to, regulations for use of human subjects, vertebrate animals, radioactive and/or biologically hazardous materials, responsible conduct of research, as well as other administrative or fiscal requirements.
  - 15) Research. The systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research).
  - 16) Research Record. The recorded data or results that substantiate the facts resulting from scientific inquiry, including but not limited to, proposals, laboratory notebooks, physical and electronic files, progress reports, oral presentations, abstracts, theses, journal articles, or any record presented as evidence to corroborate these materials.
  - 17) Retaliation. Any response by OU or an employee or agent of OU that adversely affects the employment or status of a claimant who has, in good faith, made an allegation about suspected or alleged misconduct.

**b. General Guidelines**

- 1) OU endorses high ethical standards in research and scholarship and shall investigate and resolve promptly and fairly all instances of alleged or apparent misconduct.
- 2) This policy has three basic components: 1) an initial inquiry to determine whether an investigation is warranted; 2) an investigation, if warranted; and 3) the imposition of appropriate university sanctions and/or remedies when warranted.
- 3) Potential criminal violations, such as misappropriation of federal funds, will be reported promptly to the appropriate authorities, including funding agencies.
- 4) Immediate measures will be taken to assure public welfare. In the case of potential harm to public safety or health where federal funding is involved, the Public Health Service Office of Research Integrity will immediately be notified.
- 5) An individual accused of misconduct (hereinafter the respondent) under this policy shall be accorded confidential treatment to the extent permitted by law.

- 6) As appropriate, the interim administration of research funds will be assumed by OU to ensure that the purpose of the financial assistance is carried out as specified.
- 7) In the case of funding by an external agency, OU will comply with all applicable agency regulations or requirements for addressing misconduct in science.
- 8) Where appropriate, every incident of alleged or apparent misconduct that is judged to warrant investigation (as defined in Section IV.C.) by OU will be reported promptly to any sponsor supporting the work. Incidents which progress to the stage of investigation and involve federal funding shall be reported to the PHS Office of Research Integrity within 30 days of finding that an investigation is warranted as required under 42 CFR 93.309.
- 9) OU will immediately take actions necessary to ensure the integrity of the inquiry/investigation, e.g., securing the workplace, as well as all relevant lab notebooks or scholarly records, and any other materials or property which may be of direct relevance to the investigation. This action will take place prior to or with simultaneous notification of an allegation to the respondent.
- 10) Temporary Suspensions. In cases which present potential danger to third parties, e.g., students or research subjects, or which require interim measures pending final resolution through the hearing process, OU may meet with the accused for the purpose of imposing a temporary suspension of duties without loss of pay, pending conclusion of the hearing process. At such a meeting, the respondent shall be informed of the reasons for temporary suspension and afforded the opportunity to respond to such action.
- 11) Confidentiality must be maintained for any records or evidence from which research subjects might be identified.

**c. Institutional Procedures**

- 1) Report of Alleged Misconduct. Any faculty or staff member, student, administrator, or any other person may orally or in writing report suspected scientific or scholarly misconduct to the relevant chairperson, director, college or school dean, or to the vice president for academic affairs and provost or his/her designee. OU will determine whether to conduct an inquiry of misconduct within fifteen (15) days of receiving a specific and credible allegation. Such inquiry will be completed within sixty (60) days of receiving the allegation unless documented circumstances clearly warrant a longer period. If the claimant does not wish to make his/her allegation in writing, the person receiving the allegation should transcribe the content of said allegation. All allegations of misconduct must be transcribed with the signature and date of the claimant on each page of the statement. The signed statement should be forwarded to the vice president for academic affairs and provost or his/her designee. The vice president for academic affairs and provost or his/her designee will determine whether there is a sufficient basis for conducting an inquiry. It is understood that allegations of misconduct may also be made by external granting agencies or scientific or scholarly organizations. All reports must be forwarded to the vice president for academic affairs and provost or his/her designee who will determine whether to conduct an inquiry.

2) Inquiry. The purpose of an inquiry is to determine whether an investigation of misconduct is warranted, and, if not, to respond to accusations deemed patently erroneous, frivolous and/or malicious. The purpose of the inquiry is not to reach a final conclusion whether misconduct occurred or who was responsible.

- Should the vice president for academic affairs and provost or his/her designee judge that the allegations are credible and serious, he/she or his/her designee(s) shall conduct an inquiry to determine whether an investigation is warranted. The process for the inquiry is discussed below.

If within 15 days of notice, the vice president for academic affairs and provost or his/her designee deems that an inquiry is warranted, he/she must take action to obtain custody of all research records and evidence then known to be related to the allegation of research misconduct. The respondent must subsequently be presented with written notification of misconduct inquiry and a copy of this policy. At that time, in cases of faculty, the AAUP will be informed that an inquiry has commenced. The AAUP will be provided with the name of the respondent, but not the nature of the allegation. This communication will contain the nature of the allegation and that the respondent may be accompanied by a representative or personal counsel whose role shall be limited to advising the respondent. The respondent will not be provided with the name of the claimant to the extent permitted by law unless an investigation is subsequently recommended.

- Procedures. The vice president for academic affairs and provost or his/her designee will appoint an ad hoc three-person impartial Committee of Inquiry (two of whom should be faculty).

The identities of the respondent and claimant will be kept confidential to the extent required by law. The inquiry shall be completed within sixty (60) calendar days of its initiation unless documented circumstances clearly warrant a longer period. A written report will be prepared citing the evidence reviewed and summarizing relevant testimony, if any, and reporting a conclusion of the inquiry. The respondent(s) shall receive a copy of the report and shall have opportunity to comment on it within thirty (30) days before any further action is taken or the report distributed to others.

- If OU determines that an investigation is not warranted due to determination that research misconduct did not occur based on the preponderance of evidence examined at the inquiry stage, or that the action was not intentional, knowing, or in reckless disregard, the matter of further investigation shall be closed with consideration given to appropriate remedy. The respondent shall be informed of this determination in writing. Consistent with externally mandated retention requirements, all related documents supporting the determination will be kept on file for a period of seven (7) years in the Office of the Vice President for Academic Affairs and Provost in a file separate from the respondent's regular personnel file. At the end of seven (7) years, the documents will be shredded.

3) Investigation. When OU determines that there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct, an investigation will be commenced within thirty (30) days of this determination.

- The purpose of an investigation shall be to determine whether the alleged misconduct, in fact, occurred and with intentional, knowing, or in reckless disregard of professional standards of acceptable conduct.
- The respondent will be notified prior to the commencement of investigation and presented with any new allegation found during the inquiry stage. The AAUP will correspondingly be notified that an investigation has commenced.
- Appointment of Committee. OU shall appoint an impartial ad hoc committee to conduct the investigation. The committee shall include a committee chair, plus at least two individuals who shall be members of OU's faculty, administration or staff with expertise in the research or scholarly area under investigation. OU may also appoint similarly qualified individuals from other institutions, as well as alternate or additional members as deemed useful or necessary, provided that the committee shall have an odd number of voting members in total and at least five (5) members. OU may assign an administrator to serve as non-voting staff assistant to the committee.
  - a) The respondent shall have opportunity to challenge the composition of the committee on the basis of an individual member's real or apparent unresolved personal, professional, or financial conflicts of interest with the respondent or area of research.
  - b) The respondent shall have the right to challenge the composition of the committee on the basis of an individual member's lack of expertise where that committee member is appointed to the committee as an expert in the field of research.
  - c) Members of the committee and other supporting staff shall sign statements of non-disclosure related to committee proceedings.
- Procedures. The committee shall employ procedures appropriate to the confidential nature of the investigation and designed to afford a fair opportunity to all concerned individuals to present their information and views. These procedures shall include, but need not be limited to, the following:
  - a) Once all relevant evidence has been secured at the inquiry stage and, if warranted, the charges formulated at its conclusion; the respondent(s) shall be informed, in writing, by OU that an investigation is taking place, as well as of all charges against them and the source of the allegations. The respondent shall be promptly informed of any subsequent amendment to the charges.
  - b) The respondent(s) shall be notified of the identity of the members of the ad hoc committee appointed by OU and may request that any member(s) be replaced for reasons of real or apparent conflict of interest, bias, or lack of technical expertise in the case of a research expert appointed to the committee. However, authority for the ultimate composition of the committee rests solely with OU.



- c) The respondent(s) shall appear before the committee to respond to the charges and to furnish any evidence that they deem appropriate. The respondent may be accompanied by a representative or counsel, whose role shall be limited to advising the respondent. The failure of the respondent to meet with the committee shall not deter the continuation of the investigation.
- d) All meetings of the committee with the respondent and other persons interviewed shall be recorded verbatim. The committee may prepare a transcript of some or all of the recording as part of the evidentiary record. A copy of the respondent's recorded testimony shall be provided the respondent as soon as it is available. A copy of, or access to, all evidentiary material will be given to the respondent at the time the penultimate draft of the report is provided the respondent who shall have thirty (30) days to provide comment on the report.
- e) The committee shall complete its investigation within 120 days of appointment, unless circumstances require or justify a longer period of time. If unable to complete the investigation within 120 days, OU shall request an extension from the Office of Research Integrity. During the course of an investigation, the committee shall periodically inform OU of the status of its work. If an investigation is terminated on the basis of admission of guilt, or reaching of settlement prior to conclusion, a report of this determination shall be forwarded to the Office of Research Integrity.
- f) Standard of Proof – The findings of the committee shall be supported by a preponderance of the evidence.
- g) The committee shall prepare a report of its findings, of which the respondent shall be furnished a penultimate draft and invited to comment in writing within thirty (30) days. After consideration of the respondent's comments to the penultimate draft, the committee will prepare its final draft, which shall be submitted to OU, along with all the evidence, documentation and testimony gathered during the investigation, including any written response the respondent may have submitted in response to the penultimate draft. The committee report shall be submitted to the Office of Research Integrity in the case of PHS funding or other sponsor as applies in the situation. The final report shall include:
  - Investigation Report with all attachments supporting the finding of the committee;
  - Final Institutional Action detailing the determination of the committee as to whether misconduct occurred, and if so, who committed the misconduct;
  - Findings as to whether OU accepts the investigation's findings;
  - Administrative Actions taken against the respondent upon determination that misconduct occurred and was committed by the respondent.

**d. Sanctions and Remedies**

- 1) Sanctions and Remedies. If the committee concludes that the charges are unfounded and no misconduct has occurred, and if OU concurs with these findings, the matter shall be closed, and the respondent shall be given written notice to that effect. All documentation shall be retained in the vice president for academic affairs and provost for a period of at least seven (7) years. To the fullest extent possible, OU shall seek to repair any damage that may have occurred to the reputation(s) of the respondent.

If the committee concludes that the charges are valid and misconduct has occurred, and if OU concurs in these findings, OU may impose appropriate sanctions or remedies, provided that any sanctions or remedies are in accordance with the terms of any relevant employment agreement in effect at the time the final report is issued. Remedies may include notification of journals in the case of plagiarism or misconduct involving research data or other scholarly work. If this occurs, the vice president for academic affairs and provost or his/her designee is responsible for such notification. Nothing shall prevent OU from consulting the ad hoc committee as to appropriate sanction or remedies, and OU shall have the option of asking the committee to make such recommendations as part of its official responsibility.

If OU does not concur with the findings of the committee, OU may ask the committee to engage in further investigation and fact finding which must conclude within the original time established for committee proceedings of 120 days from the date of opening the investigation of misconduct.

- 2) Appeal. Persons found guilty of misconduct may appeal through the grievance/problem adjustment mechanism of their employee group.

If no such mechanism is available, the respondent has the right to appeal the decision to the president within 30 days of the finding. In such a case, the appeal is limited: 1) improper investigation procedure, or 2) new evidence not considered in the report. In the case of an appeal, the university will request an extension of time from the external funding agency and the Public Health Service Office of Research Integrity. The president may appoint an ad hoc committee or consider the appeal himself/herself.

- 3) Report to Granting and Regulatory Agencies. In cases of funding by an outside agency, federal or other, and/or in compliance with regulatory guidelines, the appropriate agency shall be notified of the investigation upon its initiation (not an inquiry) and be kept informed of the progress of the investigation through to the final report by the vice president for academic affairs and provost or his/her designee. If federal funding is involved, a copy of the final report shall be sent to the agency and to the Public Health Service Office of Research Integrity, which may at its discretion impose additional sanctions.

**e. Indemnification**

Indemnification. OU shall defend and indemnify any and all employees, students and university volunteers who report alleged misconduct, offer testimony, serve on an inquiry or investigation committee or in any way act as an agent of the university in an inquiry or investigation of alleged misconduct in accordance with OU's policy on the Defense and Indemnification of Trustees, Officers and Employees.

### **3.4 Standards of Access to and Retention of Research Data**

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Data stewardship is a subject of wide scope that is not predictable in its application to specific circumstances, therefore, the information presented is intended to assist in recognizing situations where roles or policy need to be clarified, to identify issues that may need to be addressed, and to present options for defining responsibilities with respect to access and retention of research data.

#### **a. Definition and Ownership of Research Data**

Both the rights and responsibilities surrounding ownership, access and retention of data as well as the definition of research data, may vary based upon sponsorship of the project, nature of the funding instrument implementing the award, and general context of the situation. For the purposes of a specific research agreement, the agency's definition and expectations should be carefully reviewed as constructed within the particular agreement.

##### **1) Definition of Research Data**

The National Institutes of Health (NIH) Grants Policy Statement defines "data" as "recorded information, regardless of the form or medium on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data."

In the Office of Management and Budget's (OMB) Circular A-110, research data are "defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, excluding the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues."

Preliminary data without analysis is not included in the research data definition strictly for the purposes of access by the general public under Freedom of Information Act requirements. However, investigators must retain this raw data in laboratory notebooks or records for purposes of validating research findings. The raw data serves other purposes as well, such as patent applications or investigations of misconduct. If the research results are used for public policy or regulatory purposes the raw data may be subject to Freedom of Information Act requirements.

##### **2) Ownership of Research Data**

In general, federal policy and guidance supports institutional claims of data ownership for federally funded research. Under OMB Circular A-110, the rights to "intangible property" belong to the institutional grantee. The NIH Grants Policy Statement states that

“grantees own the data generated by or resulting from a grant-supported project.” The National Science Foundation gives grantees rights to their data as well. While federal sponsors have recognized grantees’ ownership rights in the data and research results, they retain a broad right or license to use the research results.

On the other hand, some federal and a growing number of private sector contracts, as opposed to grants, require that sponsors be granted ownership and/or unlimited, sometimes exclusive, rights in data as a condition of the award. Research institutions generally refuse to relinquish ownership and rights in data because such limits on ownership or access conflict with the goal of sharing research results to advance scholarship. At a minimum, most institutions retain rights to use the data for research and educational purposes; some institutions narrowly limit the rights assigned to research sponsors through such mechanisms as the nature of the report to be provided to the sponsor or a limited field of use for the sponsor. Before agreeing to any limits on rights and ownership, the research administrator should discuss the implications with the investigator and consider the impact on the institution’s teaching and research missions.

In its role as the grantee, the research institution is required to hold title to or own the data through its contractual obligations. Most states impose a similar ownership obligation on their state-assisted universities and research institutions. By tradition and for practical reasons, the creators of the data retain possession of the data on behalf of the institution. As custodians of the data investigators must be thoughtful about any assignments of copyrights made without consultation with the institution. Investigators should review copyright assignments usually required for the publication of journal articles or books. These assignments generally give the publisher all rights to the article or manuscript – not the data – which will limit the author’s ability to use the publication in future works. The author should retain the rights to use the publication for research and educational purposes. Institutions and investigators should carefully review the requirements of each individual award to identify any special access or retention requirements. Confusion and potential conflict may result when an institution’s intellectual property policy is silent on the issue of data ownership, but claims ownership of inventions that may be embodied in or documented through this data.

**b. Data Retention**

1) General Obligations

OMB Circular A-110 sets forth the expectations for the retention of research and administrative records produced under federal grants and cooperative agreements. Circular A-110 requires that all records – financial records and the supporting documentation, scientific data including notebooks, etc. – be maintained for three years or, in the case of litigation started before the end of the original three-year period, until any claim or audit is resolved and final action taken. Thus, a three-year period is the minimum amount of time that research data should be kept by OU. A longer period of time may be required under a specific agreement or by special circumstances given varying sponsors, regulatory (e.g., FDA regulations) or publishing company requirements. In addition, institutions may specify other exceptions to their standard data retention period such as:

- When the data are in support of a patent or other protected intellectual property, retention should extend through the life of the patent or as long as necessary to protect the intellectual property;
- When the data in question are linked to any inquiries or investigations with respect to research, such as allegations of scientific or financial misconduct or conflict of interest, the data should be retained until all charges are fully resolved; and seven years beyond this date if the investigation results in a finding of misconduct;
- If a student is involved, research data must be retained at least until the degree is awarded or it is clear that the student has abandoned the work;
- When the nature of the research data prohibits a three year retention period, e.g., biological materials that cannot be stored for a long time period. In these cases, the investigator is required to document the characteristics of the samples by some other means.

## 2) Data Storage

As the grantee and formal owner of the data, OU is responsible for retaining data as required by its agreements. However, it will not be practical or reasonable from the perspective of the investigator for the institution to assume primary responsibility for custody of the data. As a result, the principal investigator serves as the custodian of data and as responsible agent for data preservation and retention.

Institutions will want to provide adequate financial and facilities support for the retention of research data. At a minimum, policies and procedures should be developed to limit physical or electronic access to data, protect research information from accidental or intentional release to unauthorized persons, and prevent the alteration, destruction or loss of research data. Such policies and procedures must also comply with local requirements, such as state open record and medical record confidentiality laws.

## 3) Digital storage of data

OMB Circular A-110 allows substitution of copies for original documents without addressing specifically the use of electronic records. The US Department of Health and Human Services (HHS) has authorized the use of electronic imaged records as substitutions for paper records for those institutions for which it is the cognizant agency. The authorization makes it clear, however, that the use of electronic storage media requires procedures to provide for the security of the stored records including secure transmission and dissemination of the records and a process to validate the authenticity of the record. Whether records are electronic or on paper, the requirements for retrieval and access by the federal government are the same. HHS still retains the requirement that it should be notified when substituting electronic copies of original records, but not when the records are created electronically. The Office of Naval Research (ONR) and other agencies have adopted similar policies to permit substitution of electronic records.

Not all records in digital medium are copies of paper records. Research data today are both created and stored in digital media. Thus, the establishment of institutional standards for digital record storage, as well as archives for digital and other media should be considered.

### c. Data Access by Federal Agencies

1) All Data

The provisions of OMB Circular A-110, Section 53 retain the right of “timely and unrestricted access” for the awarding agency, inspectors general, and the US Controller General as a condition of all grants and cooperative agreements. Similarly, federal contracts assure access to the data by means of requirements contained within the Federal Acquisition Regulations (FARs). Access does not mean confiscation of documents. As a general rule, research institutions that receive a request for access make the original documents available for review at an institutional site or provide copies of documents requested by the agency.

2) Data used to formulate federal regulations – access via federal Freedom of Information Act (FOIA)

OU has established a procedure for responding to FOIA requests when these requests. A copy of a FOIA request will normally be sent to an institutional official and the investigator. Still, such requests should immediately be forwarded to the office of General Counsel. The institutional official will work with the investigator and the office of Grants, Contracts and Sponsored Research to ensure that any private or protected information is identified to the federal agency so that it can be protected from release. Federal agencies normally consider two exemptions to FOIA requests. Exemption 4 permits withholding of “trade secrets and commercial or financial information”. Exemption 6 permits withholding certain information, the disclosure of which “would consider a clearly unwarranted invasion of personal privacy”.

**d. Grantee Obligations for Data Sharing and Public Access**

Under some federal agency and foundation guidelines for grant funding, institutions and investigators have very clear and definitive responsibilities for the sharing of research data. These responsibilities echo the overall mission of a research institution, namely to disseminate research findings to benefit the public at large. Some examples from Federal sponsors are provided below. This list is not exhaustive but provided to demonstrate that institutions and investigators will want to review the requirements included in any agreement governing the sharing of data, materials, etc., and access to research results.

1) Data Sharing

National Institutes of Health: NIH has a number of policies that govern sharing of data, model organisms, and the dissemination of research results. Since October 2003, NIH requires a data sharing plan (or an explanation of why data sharing is not possible) be included in NIH applications seeking \$500,000 or more per year in direct costs. NIH’s policy encourages timely release and sharing of final research results (using the OMB A-110 definition above) from NIH-supported studies for use by other researchers. “Timely release and sharing” is defined as no later than the acceptance for publication of the main findings of the final data set.

NIH supports the sharing of unique research resources or research tools under reasonable terms and conditions for dissemination and acquiring the tools. The agency believes that “the sharing of synthetic compounds, cell lines, DNA sequences, etc., enhances the value of the NIH-sponsored research.” This 1999 policy embodied in NIH’s Principles and Guidelines for Recipients of NIH Research Grants and Contracts on

Obtaining and Disseminating Biomedical Research Resources complements the data sharing requirements described above.

Similarly, NIH issued a policy statement in May 2004 on the sharing of unique model organisms to ensure that the research resources developed with NIH funding are made readily available in a timely fashion to the research community. Investigators are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources. The submission of this plan is not subject to a cost threshold of \$500,000 or more per year in direct costs.

National Science Foundation: NSF Grants Policy Manual (§ 734) describes its policy on the dissemination and sharing of research results. “Investigators are expected to share with other researchers, at no more than incremental cost and within a reasonable time, the primary data, samples, physical collections and other supporting materials created or gathered in the course of work under NSF grants. Grantees are expected to encourage and facilitate such sharing.”

2) Publication Access

Federal agencies also expect that investigators will promptly prepare and submit for publication significant findings from work conducted under agency grants. In 2008, NIH issued a policy that mandates that its grantees and supported investigators provide the NIH with electronic copies of all final versions of manuscripts upon acceptance for publication if the research was supported in whole or in part with NIH funding so that the manuscripts may be archived and made accessible in a digital repository maintained by the National Library of Medicine.

3) When an Investigator Leaves the Institution, What Happens to the Data?

There are a variety of circumstances under which active and productive researchers may leave an institution. Generally, researchers will believe it is appropriate for them to take all of their research records with them. Yet, institutions are obligated to assure access to and the retention of data, and possibly to defend the value of associated intellectual property. If the departure is the result of failing tenure, or of perceived or real disputes with the institution, investigators are unlikely to take a positive view toward institutional claims to data. The challenges associated with departure of principal investigators represent another clear and, perhaps, the most compelling justification for institutions to consider the establishment and communication of policy describing rights and obligations of all parties in the management and retention of research data.

4) Other Restrictions on Data Retention and Access

Beyond the 3-year data access and retention requirements found in OMB Circular A-110 Section 53 and required by good research practice, federal regulations place additional obligations on institutions to protect and limit access to research data and information in certain specific fields. Such restricted areas include the use of select agents and toxins, personally-identifiable healthcare information, and export-controlled technologies. In addition, information and data developed under sponsored research or collaborative agreements with commercial partners, or used to support patent applications covering resulting technologies, may require access limitations and longer intervals of safeguarding.

#### **e. Patent Applications**

Although the U.S. Patent and Trademark Office rules found in Chapter 37 of the Code of Federal Regulations do not prescribe a specific period for retention, best practice requires that research data used to support a patent application should be archived for the entire 20 year patent term plus any extensions. Retention of data and other documentation is critically important to support the date of invention and claims within the application, as well as provide evidence to defend against later interference actions to invalidate a patent. In view of this expansive time interval, a growing number of institutions now require archiving of original research data and materials used to support patents and patent applications, including original laboratory notebooks, with their offices for technology licensing, with copies of the data provided to the inventor(s).

#### **f. Industry Sponsored Research**

Collaboration with industry enhances a research institution's understanding of the challenges facing industry by exposing investigators to industrial concerns and industrial approaches to research. Conversely, collaboration with research institutions helps industrial scientists to stay current in the latest developments in broad areas of basic science of strategic interest to the company. Two very different cultures interact in the collaboration between research institutions and industry.

Research agreements with industry sponsors require careful negotiations to avoid placing unreasonable or unpredictable restrictions on the access to and dissemination of research results. Universities prefer open research efforts with unrestricted publication of research results. In contrast, industry sponsors often desire limited or no publication of research results to protect the company's proprietary position. A commonly negotiated compromise regarding publication provides the industry sponsor the opportunity to review and comment on a proposed article in advance of publication. This permits the sponsor to identify proprietary information the article will disclose, and/or to delay publication for a specified period, e.g., 60 days, in order to file patent applications before publication to avoid loss of U.S. or foreign patent rights. It is essential for preserving the fundamental research and publicly available/public domain exclusion from export controls that the right to comment is only that, and it is not a right to approve the research results before they are published.

Institutions that accept some form of a confidentiality provision in their research agreements should ensure that investigators understand the restrictions and limitations that these impose. Violations of such provisions may accrue potential liability to the institution and to individual investigators for breach of contract, or possibly to individual investigators under insider trading laws. Compromise positions regarding intellectual property have been reached to satisfy the requirements of both parties. In general, universities retain title in intellectual property resulting from industry-sponsored research, with certain rights in it granted by license to the industry sponsor.



## **Chapter 4: Financial Aspects of Sponsored Projects Administration**

### **4.1 Fiscal Responsibilities of Principal Investigators (PI)**

This section is intended to define and summarize the fiscal obligations and responsibilities of principal investigators involved in sponsored activity at Oakland University (OU).

*Principal Investigator:* A principal investigator (PI) is the person designated on the External Grant Application (EGA) as the individual responsible for directing the sponsored study or project. He or she typically has experience doing similar types of research and is accountable to the funding agency for proper conduct of the study.

The PI has primary responsibility for the fiscal management of a sponsored project. The PI may delegate some duties to administrative staff; however accountability for compliance with OU and sponsor guidelines rests with the PI. Ultimately the PI is responsible for all activity on the project. Fiscal obligations related to overall project activity include adherence to all sponsor terms of award, budget preparation, oversight and management of project expenditures, submission of technical reports, effort reporting, disclosure of intellectual property, and project close out.

This policy is applicable to all faculty and staff of OU who are identified as a PI of a sponsored project.

#### **a. Budget Preparation**

When submitting a proposal to a sponsor the PI should assure that the financial figures represented in the budget are as accurate as possible. PI's should keep the following in mind when preparing budgets:

- 1) Allowability. Budgets should not include items that the sponsor or OU has deemed unallowable.
- 2) Allocable. Budgets should only include expenses directly related and necessary for the project performance.
- 3) Commitment of Effort. Proposal budgets should accurately represent the amount of time (Effort) that key personnel are committing to the project. Other OU responsibilities should be taken into consideration when preparing a budget. There should be no over commitments.
- 4) Reasonable. Budgets should only include expenses anticipated in the prudent performance of the project.
- 5) Budget Justifications. A justification should accompany each budget in order to explain the relationship of the expense to the performance of the proposed work. The explanations should focus on how this budget item contributes to the aims of the project and how the estimated costs in the budget were calculated. All budget line items should be justified.

#### **b. Oversight and Management of Project Expenditures**

When authorizing and charging expenses to a sponsored project the Principal Investigator is responsible for ensuring that:

- 1) The charge is necessary and provides a benefit to the project
- 2) The charge is allowable under sponsor and OU guidelines
- 3) Project funds are available
- 4) The charge is appropriately documented as required by university policy or sponsor terms of award
- 5) The charge has been processed through the appropriate OU departments receiving any required institutional approvals

Additionally, principal investigators (or designee) should complete a complete review of the sponsored project account monthly in order for adjustments to be made in a timely manner. Any erroneous charges must be addressed promptly and corrected by the appropriate transfer, within 90 days of ledger posting unless exceptional circumstances warrant a later transfer.

Expenditures should be monitored against the awarded budget. The responsibility for clearing overdrafts and unallowable expenses belongs to the PI and department head. If an overdraft occurs, the PI must work with the department head to identify an alternative unrestricted fund to cover the expenses which caused the error. Under no circumstances should a different sponsored project be charged for an overdraft.

If additional time is needed to complete a project and funds remain in the budget, the PI may request a no-cost extension. Requests for extensions must be initiated by the PI and processed within the terms of the award. In some cases OU officials are authorized to approve a no-cost extension, in other cases prior approval from the sponsor is required. Requests for extensions should be submitted within a month of the project end date.

### **c. Effort Reporting**

Salaries charged to sponsored projects must be supported by the appropriate level of effort. Effort is defined as the total time consumed in performance of duties. Effort includes all time spent to fulfill the obligations under a faculty appointment. This definition encompasses time spent on instruction, research, administration, committees, advising, public service, and all obligations expected in the course of performance of normal duties. Effort is not dependent upon the hours worked to accomplish the activity and must equal 100% of institutional compensated time.

Federal OMB Circular A-21 section J.10 (2) establishes criteria for acceptable methods of charging salaries and wages to federally sponsored projects. Circular A-21 requires that institutions develop a mechanism to record how individuals expend effort during a specified time period. OU complies with this federal requirement by providing after-the-fact effort reports for verification at the end of each fall, winter, and summer term. Any person charged to a sponsored project or cost share fund during the semester will appear on the effort report. The reports should be signed by the employee, principal investigator, or responsible official(s) using suitable means of verification that the work was performed. All sponsored projects receive effort

reports due to the requirement to confirm 100% of effort for personnel charged to federal awards.

Base compensation from all institutional sources is included as remuneration for effort. Compensation for incidental duties or activities outside the scope of normal duties is not apportioned to effort. Examples of activities outside the defined scope of normal duties would be supplemental pay for special lectures or teaching overload pay. Institutional base compensation includes salary apportioned to sponsored agreements. Additional pay for grant and contract activity during the academic year is prohibited. Pay outside the academic year should be apportioned in the same way as during the academic year.

#### **d. Project Close-Out**

The Office of Grants, Contracts, and Sponsored Research (GCSR) prepares and submits final financial status report with the assistance of the PI and departmental staff. Before submitting the financial report to the sponsor GCSR will forward a copy to the PI. The principal investigator should review the financial report to ensure accuracy. The PI is also responsible for ensuring that all necessary financial adjustments and documentation are received promptly after the end of the award.

### **4.2 NIH Salary Cap Information and Resource Page**

This section is intended to provide information on NIH regulations that set a maximum salary level for project personnel.

Every year since 1990 Congress has legislatively mandated a provision limiting the direct salary that an individual may receive under an NIH grant. The cap restricts the amount of direct salary to Executive Level I of the Federal Executive Pay scale. This pay scale changes each year on January 1. The annual salary cap information and associated time frames is available at [http://grants.nih.gov/grants/policy/salcap\\_summary.htm](http://grants.nih.gov/grants/policy/salcap_summary.htm). The salary cap applies to grant, contract, and cooperative awards that OU receives directly from NIH, and to those NIH awards received via a subcontract from another entity. The limitations also apply to OU's subcontractors under NIH awards.

Once a NIH award has been made the actual salary charges on the award must conform to the applicable NIH salary cap. The monthly salary amount charged to a NIH award during the academic year and/or summer cannot exceed the NIH monthly cap rate. It is also important to remember that the reported percentage of effort on a NIH award should equate to the effort committed and actually expended on the project, NOT to the percentage of salary charged. This percentage should include the effort that could not be charged to the award because of the salary cap. University funded effort is contributed as cost sharing.

Send Questions or Comments to [NIH Grants Policy Help E-mail Address](#)

### **4.3 Definitions and Categories of Sponsored Projects**

This section is intended to provide guidance in defining sponsored projects and research gifts as well as demonstrate the major categories of sponsored projects.

Both sponsored projects and research gifts are activities funded externally typically provided in response to a request or proposal. The classification of sponsored project or gift will affect (among other things) the way OU accounts for the funds.

Sponsored Projects: Sponsored Projects are externally funded activities in which a written agreement (grant, contract, or cooperative agreement) is entered into by OU and the sponsor. Sponsored projects typically have a specified statement of work. Sponsored projects typically require financial reporting and contain a sponsor-approved budget which includes direct and indirect costs. Sponsored Projects are administered by the Office of Grants, Contracts, & Sponsored Research (GCSR).

Research Gifts: Research gifts are defined as any item of value given to OU by a donor who wishes to support the university mission and who expects nothing of significant value in return, other than recognition and disposition of the gift in accordance with the donor's wishes. Gifts are tracked by University Relations and Development (URD).

**a. Sponsored Project or Gift Determination Process and Checklist**

- 1) Characteristics of a Sponsored Project:
  - Penalty may exist for non-performance of proposed activity (reversion of funds)
  - Sponsor requires return of unexpended balance
  - Detailed financial accountability is required
  - Award contains intellectual property rights provisions
  - Award restricts or monitor publications
  - Payments are contingent upon technical or fiscal reporting
  - Sponsor requests an itemized budget, typically significant revisions require sponsor approval
  - Project involves use of human subjects, vertebrate animals, radioactive materials, or recombinant DNA
  - Sponsor is a public entity
  - Period of performance is defined by the sponsor
  
- 2) General characteristics of gift:
  - Awards support a general purpose or activity not a specific scope of work with anticipated outcomes
  - No penalty exists for non-performance
  - Award does not define deliverables or something of value in return to the sponsor
  - Awards are irrevocable
  - No or minimal formal fiscal accountability to the donor
  - Generally the University is only committed to executing the donor's intent.
  - Awards do not involve the use of materials or subjects requiring regulatory compliance approval
  - Period of performance is not defined by the donor

The existence of one of these factors alone will not determine a projects classification. The preponderance of factors should be considered when deciding whether a sponsored project exists. GCSR and URD will work together when characteristics alone do not weigh towards a definite classification.

- 3) Major Extramural Categories of Sponsored Projects:
  - Research: Research activities funded by an external organization.

- Intramural Research: Support derived from OU institutional funds.  
(includes gifts, endowment interest income, operating budget and cost sharing)

GRANT	GIFT
<input type="checkbox"/> Penalty <u>may</u> exist for non-performance of proposed research; agreement states	<input type="checkbox"/> No penalty exists for non-performance. Gift may be given in support of research

expenditures)

- Instruction: Teaching and training activities funded by external organizations.
- Intergovernmental Personnel Act Agreements (IPA): A contract where OU employees may serve or cross train in federal agencies for limited periods of time.
- Public Service:
- Clinical Research:

#### 4) Evaluative Factors for Grants vs. Gifts Checklist

The following list is a summary of evaluative factors to be used in determining whether an award is considered a grant or a gift. The list is not exhaustive or a substitute for professional judgment. The factors shaded in gray may require balanced consideration of other factors. All gifts and grants in support of research activity must be considered organized research expenditures.

that a technical report or other outcome is expected to fulfill obligation.	or other activity without expectation of specific outcome.
<input type="checkbox"/> Funding is contingent upon university's commitment to expend effort or resources in fulfillment of the specific proposal.	<input type="checkbox"/> Agreement does not define a quid-pro-quo return or definitive outcome in exchange for consideration.
<input type="checkbox"/> Activity involves the use of human subjects, laboratory animals, radioactive materials or biological hazards.	<input type="checkbox"/> Gifts do not involve the use of materials or subjects requiring institutional approval.
<input type="checkbox"/> Disposition of rights to intangible property, i.e., data, licenses, patents, copyrights, are specified in the agreement.	<input type="checkbox"/> Gifts do not involve the transfer or negotiation of rights to intangible property.
<input type="checkbox"/> Sponsor is a governmental entity.	<input type="checkbox"/> Sponsor is an individual.
<input type="checkbox"/> Period of performance is defined by the sponsor.	<input type="checkbox"/> A period of performance is not defined by the sponsor.
<input type="checkbox"/> Unexpended funds are usually returned to sponsor. Grants may allow retention of unexpended funds for a specific purpose.	<input type="checkbox"/> Gifts are irrevocable. The obligation to return unexpended funds after a period of time indicates a grant.
<p><b>Sponsor is a private foundation or business entity</b> – Entity type is not a distinguishing characteristic of a grant vs. gift. Private foundations and businesses offer grants and gifts in support of research or other activities.</p>	
<p><b>Proposed scope of work binds the researcher to a specific line of inquiry or supported activity</b> – Defined scope of work is proposed and awarded. If proposal is the result of a solicitation for proposals, then the award is a grant. Unsolicited proposals should be evaluated by the preponderance of other factors enumerated on this list.</p>	
<p><b>A line item budget is substantive part of proposal</b> – A line item budget may be provided as evidence of responsible stewardship. The existence of a line item budget is not sufficient in itself to differentiate between a grant vs. gift. If penalty for deviations exist, the agreement should be considered a grant (performance indicator).</p>	
<p><b>A financial report is expected or required by sponsor</b> – A financial report may be provided as evidence of responsible stewardship. This requirement is not sufficient in itself to distinguish a gift vs. grant.</p>	

#### **4.4 Facilities & Administrative (Indirect) Cost**

This section is intended to provide an overview of facilities and administrative costs, formerly known as indirect costs.

Facilities and administrative (F&A) costs are costs incurred for common or joint objectives that cannot be readily identified with an individual sponsored project. These costs are actually incurred in OU operations that support sponsor-funded programs.

Full recovery of F&A costs is expected on all grants and contracts. It is OU policy to claim the maximum allowable reimbursement for F&A at a federally negotiated rate. This applies to all sponsored projects generating F&A (indirect) costs.

Procedures: Proposals submitted to the Federal Government or non-federal sponsor should include F&A costs at the full federally negotiated rate except when the sponsor's rate is specified or the nature of the project excludes F&A. Any F&A rate that differs from those mentioned above must have the written approval of the Vice Provost for Research prior to submission to the sponsor.

It is understood that some sponsors have policies regarding limitations on F&A costs. In cases where a sponsor has an official policy regarding a limit on F&A costs OU will accept those requirements. The sponsor's policy statement or program solicitation reference should be submitted with the proposal.

Related Form: OU's current F&A ([Attachment 4a](#))

#### **4.5 Facilities & Administrative Cost Waivers and Waiver Request**

##### **a. F&A (Indirect) Cost Waiver**

This section is intended to provide a waiver process in which a Principal Investigator (PI) can request administrative approval for a reduction in the F&A Cost from a prospective sponsor.

Generally, the full applicable OU F&A rate should be included in the proposal budget. Collection of anything less than the full amount of F&A costs will result in OU not being reimbursed for the total costs required to conduct the project. Thus, a waiver of any portion of F&A cost must be approved in advance of proposal submission by the designated OU official.

This applies to any Principal Investigator requesting a reduction or waiver of F&A (indirect) costs.

##### **b. Procedures**

In certain circumstances, the Vice Provost for Research may approve a reduction or waiver of the F&A rate normally utilized for sponsored projects. Generally, in order to request a reduction a waiver must be obtained, completed, and submitted prior to submitting the associated proposal to the Grants, Contracts, and Sponsored Research Office (GCSR). The waiver should be processed as early as possible in order for the PI to finalize his/her budget with the proper F&A rate.

It is understood that some sponsors have policies regarding limitations on F&A costs. In cases where a sponsor has an official policy regarding a limit to F&A costs OU will accept those requirements. The sponsor's policy statement or program solicitation should be submitted to GCSR along with the proposal.

The routing of the waiver request is as follows:

- 1) Principal Investigator drafts and signs the request
- 2) Forward to the department chair (or equivalent) for review and signature
- 3) Forward to the college dean (or equivalent) for review and signature
- 4) To the Office of Grants, Contracts, and Sponsored Research for final determination.

Related Form: Facilities & Administrative Cost Waiver Request ([Attachment 4b](#))

#### **4.6 Charging Administrative and Technical Expenses**

##### **a. Administrative and Technical Expenses**

This section is intended to provide guidance in regards to charging administrative and clerical support expenses to sponsored research.

Salaries for administrative or clerical staff and general operational expenses, such as local telephones, should be included as part of indirect costs. Direct charging of administrative and clerical salaries may be allowed as direct costs when the nature of the work performed for a specific project requires an extensive amount of administrative or clerical support which is greater than the routine level of services generally provided by the academic unit. Administrative and technical costs must also be readily and specifically identified with the project with a high degree of accuracy. The circumstances requiring direct charging of these types of costs must be justified to the awarding agency as part of the original proposal.

##### **b. Procedures**

To avoid disallowance of such charges, sponsor approval should be secured when the budget and justification are submitted for sponsor review. Agency approval will be assumed if the proposal contains a substantive justification of the expense as reasonable and allocable to project and the expenses are not specifically denied in the award documentation to the University. If a specific justification cannot be clearly stated, these costs should not be included in the proposed budget submitted to a sponsor.

#### **4.7 Subawards**

##### **a. Awarded Funds**

This section is intended to clarify the Subaward process at OU.

When funds are awarded to OU through a sponsored project are to be paid to an outside entity the arrangement should be treated as a subaward if all of the following criteria apply:



- 1) The subaward's key person is acting as a collaborator or co-investigator and contributing a significant portion of the scope of work.
- 2) Subrecipient does not provide similar services as their primary business
- 3) Verification by OU's Principal Investigator of the subrecipient's performance is required before payment is made.

If any of the above criteria do not apply, funds must be paid using a purchase order. This policy applies to any sponsored project in which a Principal Investigator is requesting a subaward.

The guidelines for subawards issued by a prime should define institutional roles and responsibilities as well as address subrecipient monitoring. Adequate guidelines should also include documentation for pre-award review, life of the award, and close-out procedures.

#### **b. Pre-Award Review**

- 1) Obtain an official subrecipient proposal
  - Statement of work
  - Deliverables
  - Budget and budget justification (including any required cost-sharing)
  - Should contain a letter of commitment or be approved by an authorized official
- 2) Review subrecipient institution's A-133 Audit (Federal Audit Clearinghouse)
  - Download most recent audit from online site
  - Should be signed and dated by reviewer
  - If data is older than 2 years must request latest audit from the subrecipient
  - For non-A133 request most recent audit or obtain a certification
  - If an audit contains findings request and review a corrective plan
- 3) Review the debarred and suspended list
  - Each subaward should contain a statement indicating that the subrecipient is not debarred or suspended from receiving federal funds
  - If subrecipient appears on the list must find alternative method of completing work
- 4) Negotiate terms and conditions
  - Any applicable terms and conditions from the sponsoring agency to the prime should flow down to the subrecipient
  - Should also include specific terms from the prime (i.e. invoicing, reporting, closeout, access to records/financial statements for auditing, etc)
  - Subaward should contain the CFDA number and name of federal agency

\*\* If the subaward was not submitted in the proposal to the sponsor prior approval and sole source justification may be needed.

#### **c. Life of the Subaward (monitoring)**

- 1) Upon receipt of a fully executed agreement
  - A purchase order for the entire amount of the subaward should be prepared by the Principal Investigator's department. (Encumbered funds ensure availability.)

- The purchase order must be forwarded to GCSR for approval
- The first \$25,000 is subject to indirect costs.

2) Invoice monitoring

- Invoices should be sent directly to GCSR from the subrecipient
- GCSR will check for: fully executed subaward agreement, appropriate invoice format, any required cost share, and subrecipient approval

\* If any of the above is unsatisfactory the subrecipient will be notified for corrections.

\* If all of the above are sufficient the invoice will be copied and the original will be forwarded to the PI's department for approval.

3) The PI or designee is responsible for:

- Reviewing and approving invoices
- Making sure that the invoice is in accordance with the proposed budget
- Ensuring that the subrecipient is adhering to the terms and conditions of the subaward
- Verifying that the costs are reasonable and allowable

\*The PI or designee's signature on the invoice/VPA/DPV indicates that such a review has taken place.

\*The PI should not approve an invoice if technical reports, deliverables, or any other reports are delinquent.

4) Once an invoice has been approved

- The PI should forward it back to GCSR
- GCSR will: verify grant and account number, check budget availability, verify Period of performance, approve and forward to Accounts Payable for payment, and the encumbrance will be reduced by invoiced amount

**d. Close-Out**

- 1) Close-out should be timely (60-90 days)
- 2) Verify the end date
- 3) Obtain an invoice marked "final"
- 4) De-obligate any remaining encumbrance
- 5) Verify all cost share requirements (if any)
- 6) Obtain all required reports (i.e. invention, property, technical (PI), release, etc)
- 7) Verify audit (sign & date)

**4.8 Cost Sharing**

This section is intended to provide guidance on cost sharing procedures at OU.

**a. Definitions**

Cost sharing is that portion of total project costs that are paid from sources other than the sponsor. Cost sharing can also be known as “in-kind” or “matching”. All these terms can refer to cash contributions, donated services, or facilities. In general, cost sharing is considered to be all costs listed in the budget that are not requested from a potential sponsor.

Mandatory cost sharing represents expenses that are paid from non-sponsor funds that were required as listed in the solicitation or costs that that were clearly shown in the approved proposal budget as OU share.

Voluntary cost sharing includes expenses that have been contributed by OU to the project in excess of the sponsor’s requirements or those listed in the approved budget.

Pledges of cost sharing are real commitments of university resources. Thus, cost sharing should only be listed in a proposal budget when it is mandated by the sponsor in writing. The Office of Grants, Contracts, and Sponsored Research highly discourages any other cost sharing requests.

**b. Procedures**

Due to federal regulations mandatory cost sharing expenses must be well documented and tracked allowable project costs.

**c. Pre-Award**

When cost sharing is mandated by a sponsor the commitment must be verified at the time the proposal is submitted. The cost share amount should be included in the proposal budget as well as listed on the External Grant Application (EGA) indicating the source of funds. An OU fund number is preferred.

**d. Post-Award**

All grant awards with mandatory cost sharing requirements must have a cost share fund(s) set up in the OU financial system (Banner). These cost share funds are linked to the grant fund in Banner. Multiple cost share funds may be needed to track different sources of cost sharing dollars, and to track cost sharing for multiple departments working together on a grant project.

The following predecessor funds are used to identify types of cost share funds.

- R650 Cost Share Restricted Fund
- G400 Cost Share General Fund
- D800 Cost Share Designated Fund

**e. Examples**

- 1) If the cost share commitment is in-kind salary, the cost share dollars would be coming from a university general fund, therefore, the Banner cost share fund would have a Pred fund of G400 (Cost Share General Fund).
- 2) If the cost share dollars are coming from a departmental discretionary fund, the Banner cost share fund would have a Pred fund of D800 (Cost Share Designated Fund).

- 3) If the cost share dollars are coming from an external agency and are specifically designated for the grant cost share requirements, the Pred fund would be R650 (Cost Share Restricted fund).

Multiple cost share funds roll up to the grant in the Banner Grant Module. The Grant Inception to Date form (FRIGITD) can be used to view a summary of all the grant expenditures (including all cost share funds), and also provides detail for each individual fund that rolls up to a grant.

In most cases it is easiest to document salaries and the associated fringe benefits. In order to allocate budgets for in-kind salary cost share, the department should prepare a Change of Status Form for all the employees whose salary will be reported as cost share. This is usually done by allocating a specific percentage of the employee's salary to the grant cost share fund. When completing the Change of Status, make a note in the comments section of the Change of Status Form that the reason for the change is to track grant cost sharing. The Budget Office will transfer the salary budget, and the Payroll Office will charge the actual salary expense to the new cost share fund. This will insure that the Time and Effort Reports will accurately reflect the effort committed to each granting agency. The Change of Status forms will need to be prepared each fiscal year in order to properly allocate salary over the entire grant project period.

If the cost share commitment is for supplies, services, or equipment, the GCSR staff will enter the cost share budget in Banner. The department or school providing the cost share funds will then prepare a journal voucher (jv) to transfer the dollars to the cost share fund using the sub-account Y079\*. The related expenses should be posted directly to the cost share fund whenever possible by DPV, PO, VPA, etc. If a journal voucher must be done to move the expenses, the jv must be sent to GCSR for approval, and must be accompanied by supporting documentation and an detailed explanation as the why the expense is being transferred by jv.

#### **f. Close-Out**

Designated and restricted cost share funds will be cumulative throughout the entire grant project period, but general cost share funds are subject to fiscal year close-out procedures. At fiscal year end, GCSR will provide a list of general cost share funds to the Budget Office for review. The Budget Office will prepare any necessary one-time salary and fringe benefit jv's as required for fiscal year close-out. At this time, the departments may need to prepare Change of Status Forms for the new fiscal year allocation.

At the conclusion of the grant project period, the grant fund and all related cost share funds must be reconciled and made inactive in the Banner system. The department must submit Change of Status Forms to remove all personnel from the grant funds as of the grant end date. GCSR will reconcile and close-out the grant fund, designated cost share funds, and restricted cost share funds. The Budget Office will reconcile and close-out the general cost share funds, upon notification by GCSR that the grant is expired.

**\*Please note: The sub-account Y079 should never be used to transfer money or expenditures directly into the main grant fund, it should be used for cost share funds only.**

#### **4.9 Control of Property**

This section is intended to provide guidance in regards to equipment purchases at OU

**a. Definition**

Nonexpendable property is any movable fixed asset that meets the following criteria:

- 1) Costs \$5,000 or more per item, or is a component part of another piece of equipment
- 2) Has a useful life of two years or more

For complete OU guidelines regarding equipment please see Administrative Policy #360 <http://www2.oakland.edu/audit/POLCY360.HTM> ([Attachment 4c](#))

**b. Procedures**

All equipment obtained by the university or provided for use under a sponsored agreement is subject to university control and must be maintained and disposed of only in accordance with established OU policies and procedures as outlined in Administrative Policy #360. Departments obtaining equipment are responsible for its use, maintenance, and disposal. Departments are also responsible for notifying Property Control of any changes in equipment status such as transfers or disposals.

**4.10 Fringe Benefits and Rates**

This section is intended to provide information regarding fringe benefits at OU

**a. Definition**

Fringe benefits include such items as social security, workers compensation, university retirement programs, and health insurance. These rates are also negotiated with the Federal government (refer to attachment 4b) by OU Finance Administration.

## COLLEGES AND UNIVERSITIES RATE AGREEMENT

EIN #: 1381714400A1

DATE: November 18, 2008

INSTITUTION:  
 Oakland University  
 Office of Finance & Administration  
 520 O'Dowd Hall  
 Rochester MI 48309-4401

FILING REF.: The preceding  
 Agreement was dated  
 November 17, 2008

The rates approved in this agreement are for use on grants, contracts and other agreements with the Federal Government, subject to the conditions in Section III.

SECTION I: FACILITIES AND ADMINISTRATIVE COST RATES\*

RATE TYPES: FIXED FINAL PROV. (PROVISIONAL) PRED. (PREDETERMINED)

TYPE	EFFECTIVE PERIOD		RATE (%)	LOCATIONS	APPLICABLE TO
	FROM	TO			
FINAL	07/01/05	06/30/08	44.5	On Campus	Organized Research
FINAL	07/01/05	06/30/08	44.5	On Campus	Instruction
FINAL	07/01/05	06/30/08	26.0	On Campus	Other Spon. Act.
FINAL	07/01/05	06/30/08	26.0	Off Campus	All Programs
PRED.	07/01/08	06/30/12	48.0	On Campus	Organized Research
PRED.	07/01/08	06/30/12	48.0	On Campus	Instruction
PRED.	07/01/08	06/30/12	31.0	On Campus	Other Spon. Act.
PRED.	07/01/08	06/30/12	26.0	Off Campus	All Programs
PROV.	07/01/12	UNTIL AMENDED	Use same rates and conditions as those cited for fiscal year ending June 30, 2012.		

\*BASE:

Modified total direct costs, consisting of all salaries and wages, fringe benefits, materials, supplies, services, travel and subgrants and subcontracts up to the first \$25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, tuition remission, rental costs of off-site facilities, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of \$25,000.

(1)

INSTITUTION:  
 Oakland University  
 Office of Finance & Administration

AGREEMENT DATE: November 18, 2008

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**SECTION I: FRINGE BENEFITS RATES\*\***

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RATE TYPES: FIXED      FINAL      PROV. (PROVISIONAL)      PRED. (PREDETERMINED)

TYPE	EFFECTIVE PERIOD		RATE (%)	LOCATIONS	APPLICABLE TO
	FROM	TO			
FIXED	07/01/08	06/30/09	38.8	All	Full-Time Employees
FIXED	07/01/08	06/30/09	7.6	All	PT/Temp Employees
FIXED	07/01/09	06/30/10	40.0	All	Full-Time Employees
FIXED	07/01/09	06/30/10	7.5	All	PT/Temp Employees
PROV.	07/01/10	UNTIL AMENDED	Use same rates and conditions as those cited for fiscal year ending June 30, 2010.		

INSTITUTION:  
Oakland University  
Office of Finance & Administration

AGREEMENT DATE: November 18, 2008

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SECTION II: SPECIAL REMARKS

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TREATMENT OF FRINGE BENEFITS:

The fringe benefits are charged using the rate(s) listed in the Fringe Benefits Section of this Agreement. The fringe benefits included in the rate(s) are listed below.

TREATMENT OF PAID ABSENCES:

Vacation, holiday, sick leave pay and other paid absences are included in salaries and wages and are claimed on grants, contracts and other agreements as part of the normal cost for salaries and wages. Separate claims for the costs of these paid absences are not made.

OFF-CAMPUS DEFINITION: For all activities performed in facilities not owned by the institution and to which rent is directly allocated to the project(s), the off-campus rate will apply. Grants or contracts will not be subject to more than one F&A cost rate. If more than 50% of a project is performed off-campus, the off-campus rate will apply to the entire project.

Equipment Definition -

Equipment means an article of nonexpendable, tangible personal property having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit.

FRINGE BENEFITS:

FICA  
Retirement  
Disability Insurance  
Worker's Compensation  
Life Insurance  
Unemployment Insurance  
Health Insurance  
Dental Insurance  
Optical  
FSA-Employer Match  
Longevity  
Sick time Payout  
Tuition Waivers



INSTITUTION:  
Oakland University  
Office of Finance & Administration

AGREEMENT DATE: November 18, 2008

SECTION III: GENERAL

A. LIMITATIONS:

The rates in this Agreement are subject to any statutory or administrative limitations and apply to a given grant, contract or other agreement only to the extent that funds are available. Acceptance of the rates is subject to the following conditions: (1) Only costs incurred by the organization were included in its facilities and administrative cost pools as finally accepted; such costs are legal obligations of the organization and are allowable under the governing cost principles; (2) The same costs that have been treated as facilities and administrative costs are not claimed as direct costs; (3) Similar types of costs have been accorded consistent accounting treatment; and (4) The information provided by the organization which was used to establish the rates is not later found to be materially incomplete or inaccurate by the Federal Government. In such situations the rate(s) would be subject to renegotiation at the discretion of the Federal Government.

B. ACCOUNTING CHANGES:

This Agreement is based on the accounting system purported by the organization to be in effect during the Agreement period. Changes to the method of accounting for costs which affect the amount of reimbursement resulting from the use of this Agreement require prior approval of the authorized representative of the cognizant agency. Such changes include, but are not limited to, changes in the charging of a particular type of cost from facilities and administrative to direct. Failure to obtain approval may result in cost disallowances.

C. FIXED RATES:

If a fixed rate is in this Agreement, it is based on an estimate of the costs for the period covered by the rate. When the actual costs for this period are determined, an adjustment will be made to a rate of a future year(s) to compensate for the difference between the costs used to establish the fixed rate and actual costs.

D. USE BY OTHER FEDERAL AGENCIES:

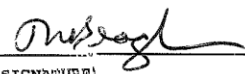
The rates in this Agreement were approved in accordance with the authority in Office of Management and Budget Circular A-21 Circular, and should be applied to grants, contracts and other agreements covered by this Circular, subject to any limitations in A above. The organization may provide copies of the Agreement to other Federal Agencies to give them early notification of the Agreement.

E. OTHER:

If any Federal contract, grant or other agreement is reimbursing facilities and administrative costs by a means other than the approved rate(s) in this Agreement, the organization should (1) credit such costs to the affected programs, and (2) apply the approved rate(s) to the appropriate base to identify the proper amount of facilities and administrative costs allocable to these programs.

BY THE INSTITUTION:

Oakland University  
Office of Finance & Administration  
(INSTITUTION)

  
(SIGNATURE)

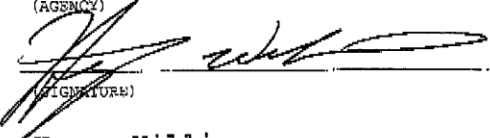
John W. Beaghan  
(NAME)

Vice President for Finance and Administration  
(TITLE)

November 19, 2008  
(DATE)

ON BEHALF OF THE FEDERAL GOVERNMENT:

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
(AGENCY)

  
(SIGNATURE)

Henry Williams  
(NAME)

DIRECTOR, DIVISION OF COST ALLOCATION  
(TITLE) CENTRAL STATES FIELD OFFICE

November 18, 2008  
(DATE) 5061

HHS REPRESENTATIVE: Narendra B. Gandhi  
Telephone: (214) 767-3230

# Oakland University

Attachment 4b

## REQUEST FOR FACILITY & ADMINISTRATIVE COST REDUCTION OR WAIVER

Principal Investigator:

Department:

Project Title:

Sponsor:

Proposal Due Date:

Request (*check one*):  Full Waiver  Rate Reduction to \_\_\_\_\_ % of Base:

Direct Cost Requested: \_\_\_\_\_ \$

Indirect Cost Recovery if Institution's Normal Rate is used: \$

Indirect Cost Recovery if Requested Rate/Waiver is used: \$

Loss to the Institution: \_\_\_\_\_ \$

Justification for Request:

PRINCIPAL INVESTIGATOR: \_\_\_\_\_ Date: \_\_\_\_\_  
*Signature*

CHAIR/DIRECTOR: \_\_\_\_\_ Date: \_\_\_\_\_  
*Signature*

DEAN: \_\_\_\_\_ Date: \_\_\_\_\_  
*Signature*

VPR: \_\_\_\_\_ Date: \_\_\_\_\_  
*Signature*



# Oakland University

## Administrative Policies and Procedures

**NUMBER:** 360

**SUBJECT:** PROPERTY MANAGEMENT

**AUTHORIZING BODY:** PRESIDENT'S CABINET

**RESPONSIBLE OFFICE:** UNIVERSITY SERVICES

**DATE ISSUED:** MARCH, 1988

**LAST UPDATE:** MARCH, 2002

**RATIONALE:** The following Property Management Section relates to the acquisition, screening, identification, use, care, maintenance, special handling, inventory, transfer, disposition, storage, capitalization, and responsibilities of property and the Office of Property Management.

**POLICY:**

**OVERVIEW OF PROPERTY MANAGEMENT**

The University operates a property control system that identifies all nonexpendable property. The Property Management Office is part of Police & Materials Management and is responsible for maintaining the records of all nonexpendable property (i.e. equipment) in the possession or custody of the University. Therefore, all nonexpendable property must be reported to the Property Management Office upon acquisition.

Federal Circular Number A-110, available on the website: [www.omb.gov](http://www.omb.gov), prescribes uniform standards governing management of property awarded by grants or agreements by the Federal Government. OU will observe these standards when applicable.

Nonexpendable property is any fixed asset that meets all of the following criteria:

- Costs \$5,000.00 or more per item, or is a component part of another piece of equipment;
- Has a useful life of two years or more; and
- Is not materially changed through use.

## TITLE

Title to or ownership of all University property or material purchased with University funds is vested in OU. No department, division, school, college or any other unit of the University owns any property. Such units may have property in their custody, but title rests either with the University or with the outside agency which has loaned the property to the University for specific purposes.

Title to property purchased with contract or grant funds is vested in accordance with the provisions of the specific contract, grant or agency policy.

## RESPONSIBILITY

A. The University is responsible for all the material to which it holds title. Custodial responsibility for other material rests with the University to the extent that it has explicitly agreed to accept responsibility thereof.

The University's Property Management Office is responsible for maintaining all pertinent information about each item of nonexpendable property on hand, whether purchased with University, grant, or contract funds. It is the responsibility of the Property Manager to implement and administer procedures in all areas of the University having custodial responsibility for University and/or government property and provide maximum utilization of all material.

## PURCHASE

Inventoriable property is acquired by purchase requisition and purchase order, and is recorded in the university's computer system. **SOP's can be used for equipment up to \$1,000** (see note below on S080 account). This equipment will not be inventoried or covered by the university's insurance program. To acquire equipment, departments are to follow the University's regular purchasing procedure (see policy #1000). When purchasing equipment an account beginning with an "S" (S001, S002, etc.) must be used on the purchase requisition. If the equipment is a component part to a piece of equipment purchased previously, the account used on the original purchase requisition should be used for the component purchase e.g. S005 - computer purchase (original purchase), S005 - tape drive (component) for the computer. The S080 account is to be used for non-inventoriable equipment. (Equipment which costs less than \$2,500, is not considered necessary to insure, or is not a component part to another piece of equipment).

## GIFTS

Inventoried property acquired by gift is assigned a property number and recorded by the Property Management Office. The date the gift is accepted is considered as the date of acquisition. No gift should be recorded by Property Management until a copy of the Gift Memorandum is received from Gift Accounting Office (see policy 500).

Upon receipt of such a memorandum, the item will be identified by decal number; however, no amount or acquisition cost will be insured unless such an amount is identified on the memorandum.

Gifts of art and/or scientific collections are recorded on a multiple item or group basis by the Property Management Office. Gifts of bound volumes, pamphlets, documents and other collections are recorded by the Library and do not become a part of the Property Records.

## **FABRICATED EQUIPMENT**

Inventoried property which has been fabricated by a department of the University is reported to the Property Management Office by the department having fabrication responsibility. The information should include a complete description of the item, the location, name and account number of the department that is to have custodial responsibility, and the value of the equipment. The value assigned to the property is the sum total of all of its component parts, both inventoried and non-inventoried, and all other supplies and materials, labor costs, freight and insurance as applicable.

If the fabricated equipment consists of components which have been purchased on Purchase Orders, the Property Management Office will retain copies of the purchase orders until a fabrication report is received. The report should include all of the above referenced information allowing for accurate capitalizing of the equipment upon completion.

## **SCREENING FOR GOVERNMENT PROPERTY**

OU is required by specific provisions within OMB A-110, and specific requirements of the Office of Naval Research to adopt an effective equipment management program to insure that costly research equipment is fully utilized and that unnecessary equipment purchases are avoided. Careful screening of material and property should take place prior to the purchase of equipment to insure that the equipment is needed and that the need cannot be satisfied with the equipment already in the possession of the University.

The requirements of this policy have an effect on University purchases of equipment as well as research activities of the University. It is to be understood that any shared use of equipment is to be conducted on a NONINTERFERENCE basis only, and that the Principal Investigators, Department Heads and/or Budgetary Heads reserve the right to insure that their units or projects are not adversely affected through the shared use of equipment.

For department or unit screening, inventory records for all equipment accountable or under the custody of a department or unit will be furnished annually by the Property Management Office.

Requisitions for federally funded capital equipment will be screened prior to issuance of a purchase order in order to avoid duplication and unnecessary capital equipment purchases. The guidelines and responsibilities for completing the screening requirements are listed as follows:

Screening for property value of \$2,500 to \$9,999 will be carried out by the department or unit and will be restricted to screening of like equipment under the custody of that department or unit. The Property Management Office is available to assist in this category of equipment.

Screening for property with a unit value of \$10,000 or more will be carried out by a joint effort of the department or unit and the Property Management Office. This screening will encompass the total pool of like property under the custody of the University.

## **RECEIPT OF PROPERTY**

When receipt is made through the University Shipping/Receiving Department, the Shipping/Receiving Department determines that the number of packages corresponds to the freight bill, bill of lading or purchase order, and that there is no visible damage. The buying department, upon receipt of the property, makes a thorough inspection of the property to determine that it is as ordered and that there is no concealed damage. If the shipment is complete and in good order, the receiving documentation is signed. The document constitutes a delivery report. If the shipment is not in order, discrepancies incident to the shipment are noted and the Shipping/Receiving Department and the Purchasing Department are notified. In the case of Government Property, the Property Management Office should be promptly notified.

When the quantity or description of property received differs from the quantity or description noted as shipped on the shipping document, only that quantity and nature of property actually received is recorded on the official receiving and property records.

## **IDENTIFICATION OF UNIVERSITY INVENTORIED PROPERTY**

Property which is to be included in the University inventory must satisfy the definition of equipment and requirements for capitalization. The Property Manager will make the determination as to whether or not these requirements are satisfied.

All inventoried property is identified, marked with a property number and recorded promptly upon receipt. It shall remain so identified as long as it is in the custody, possession or control of the University. Such markings and identification are removed or obliterated from the property recorded only when sold, scrapped, or otherwise disposed of.

The application of the property number to the material or equipment is the responsibility of the Property Management Office; however, this function may be delegated to the custodial department when deemed necessary by the Property Management Office and agreed upon by the department. The custodial department must make the property number(s) available to the Property Management Office within thirty (30) days. If the information is not made available within 30 days, the additional costs incurred by the Property Management Office relating to the assignment and procurement of the property numbers will be passed on to the custodial department.

The property number is applied to the actual unit unless its size or nature makes it impractical. The property number should be affixed to the equipment adjacent to the manufacturer's name plate or in a position for easy identification. An identification number is never to be affixed to an item in such a manner as to deface the item or to appear obtrusive to the decor of an office or artistic display.

Identification is normally effected by affixing a decal or other legible, permanent, conspicuous and tamperproof method. If additional identification is considered necessary, it should be applied in a manner that will avoid confusion with the property number.

Should the identification number accidentally or mistakenly be obliterated, defaced or removed, the property shall be marked again with a new number. Caution shall be taken by the custodial departments and the Property Management Office to insure that the old number has been removed from the system.

Should an item of property be too small to effectively be tagged with a University decal, the item will be identified as normal, but the decal number will be assigned for capitalization purposes only. The property records shall be noted with the words "can't tag."

### **IDENTIFICATION OF GOVERNMENT INVENTORIED PROPERTY**

Each controlling department is responsible for identifying, marking, and recording Government Inventoried Property promptly upon receipt. For the purposes of identification, the Property Manager may furnish decals, plates or tags for attachment to the property. Other means of marking are applied with the approval of the Property Manager. The property remains so identified as long as it remains in the custody, possession or control of the University. Unless already marked, all Government-owned property will be marked with the designation of the Government agency responsible for control functions and funding, and a Government identification number, unless the size or nature of the property makes it impractical or the property is an accessory or auxiliary and attached to or otherwise made a part of an item of equipment and is required for normal operations. In all latter cases, such items are entered and described on the department records of the original property to which it is attached or of which it is otherwise a part. In case of items included within a standard registration system, e.g., automotive, construction, or material handling equipment, application for the proper registration number is made to the appropriate Federal Government Agency, which number may be used in lieu of any other identification number.

### **IDENTIFICATION OF GOVERNMENT PROPERTY OTHER THAN GOVERNMENT INVENTORIED PROPERTY**

Identification, marking and recording of Government Property, other than that designated as Government Inventoried Property is the responsibility of the custodial department, the Principal Investigator and the Property manager. Questions regarding the applicability of this policy should be addressed to the Property Manager.

### **EQUIPMENT USE, CARE, AND MAINTENANCE**

Departments are responsible for the care, maintenance, and use of all equipment in their custody. For equipment acquired under grants and contracts, the Principal Investigator shares this responsibility with the department.

Care and maintenance includes periodic inspection, regularly scheduled lubrication, protection from exposure, and proper cleaning prior to storage. The goal is to maintain the efficiency and usefulness of the equipment for as long as possible. Records should be kept of maintenance and deficiencies revealed during periodic inspection. (Principle Investigators should be aware of any specific equipment care and maintenance requirements by grants or contracts.)

## **INCREASED USE THROUGH SHARING**

Scientific equipment with a cost over \$5,000 should be made available for sharing if it is not fully utilized by the department responsible for the equipment. When reported to the Property Management Office, the equipment will be added to a listing of Scientific Equipment Available for Shared Use.

### Scientific Equipment Available for Shared Use

To avoid unnecessary expenditures for scientific equipment costing over \$5,000, a listing of Scientific Equipment Available for Shared Use is to deans and department chairpersons upon request. This list should be checked before submitting a Request to Purchase such equipment. Arrangements for sharing should be made through the Property Management Office.

### Guidelines for Shared Usage:

1. The terms of all shared use arrangements, including utilization schedules, are to be agreed upon in advance by the departments and/or individuals involved.
2. Rental fees may not be charged to a department for the shared use of any University-owned equipment acquired with federal funds. However, reasonable maintenance, repairs, calibration, or other costs directly related to the shared use may be passed on.

## **EQUIPMENT ACQUIRED UNDER GRANTS AND CONTRACTS**

Property acquired with contract or grant funds, but title to which vests immediately with the University, shall also be identified with the contract or grant number until completion of the contract or grant. Identifying these items as contract or grant property is the responsibility of the contract or grant office. These items are commingled with all other university property within the Property Management inventory system.

During the period of a grant or contract, the Principal Investigator determines the utilization of equipment acquired. After the grant or contract expires, the department chairperson may suggest a use which will be beneficial to the overall departmental program or the dean may recommend University priorities for the equipment. Federal agencies retain the authority to define the use and transfer status of agency-owned equipment.

Federally funded grants and contracts holdings shall be inventoried at least once a year by the custodial department. A bi-annual audit will be conducted by the Property Management Office. The custodial office shall affix a government ID number to nonexpendable property to which title is held by the government. This government ID number is on a separate decal next to the decal bearing the University ID number.

Property management will assist the Research and Academic Development Offices in reviewing requests to transfer equipment purchased under a grant or contract. This review is used to determine whether the University holds title to the equipment, and whether any stipulations of the grant or contract would prohibit a transfer.

An Inventory Release Form, available through University Services (Printing and Reprographic Services) is used to initiate transfers and disposals. The signature of the responsible Principal Investigator and Grant/Contract Administrator is required.



Where equipment title has remained with a federal agency the Grant/Contract Administrator must request disposal instructions from the appropriate federal agency. The disposal instructions will either relieve the University of further accountability; request that equipment be returned to the agency; or request that it be sold and that the proceeds be returned to the original agency less \$100 or 10% of the proceeds, whichever is greater, for selling and handling expenses. The Property Management Office will expedite disposal actions upon receipt of these instructions.

Reports on equipment acquired through Grants or Contracts is the responsibility of the Grant/Contract administrator.

### **PROPERTY RENTED OR LEASED**

Property acquired by rent, lease with option to purchase, or other types of installment purchases, is recorded at the total cost and assigned a property number. The property number will not be affixed to the item until purchase is made by the University, however, the assigned property number will serve to identify the equipment throughout the utilization period or until purchase.

### **PERSONALLY OWNED PROPERTY**

If a University employee keeps personally owned property on campus, it should be reported to the Property Management Office and identified as the property of the individual. The University is not responsible for the loss of or damage to said property.

### **LOAN PROPERTY**

If property is loaned to another department for a period of six months or more, it should be reported to the Property Management Office on an Inventory Release Form (See Appendix A), giving the name of the borrowing department, the property number (decal), and the new location of the property. Signatures of both department heads are required for approval of the transaction.

Loan of property to faculty, staff or students for off-campus use in a University program must have prior written approval from the department head or dean.

The link to the "request to take equipment off campus" form is available by clicking on the following link:

[http://www2.oakland.edu/uns/files/remove\\_equipment\\_form.pdf](http://www2.oakland.edu/uns/files/remove_equipment_form.pdf)

A memorandum can be sent to the dean or department head which:

- Identifies the equipment (description and inventory number)
- Explains the need
- Identifies the location
- Identifies the individual
- States the time period

If approved, he/she must endorse the memorandum and forward a copy to the Property Management Office and the custodial department. During the period of the loan to any of the above mentioned, the stated property becomes the liability of the individual having custody.

When the loan is terminated, the Property Manager must be informed by the lending department, and accountability returned to the custodial department.

Any loan of property to an external organization must have the prior approval of the head of the custodial department and the Property Manager. The Inventory Release Form will be used for approval. When the property is returned, the Property Management Office should be notified by the lending department and accountability returned.

The loan of property by non-governmental organizations for demonstration or approval purposes is not recorded by the Property Management Office. Long-term loans of property for research purposes will be identified by the sponsor's ID number.

### **UNIVERSITY PROPERTY INVENTORIES AND AUDITS**

A physical inventory of all capital equipment will be taken and the results reconciled with the property records every other year. Any difference between quantities determined by the physical inspection and those shown in the property records must be investigated to determine the cause of the difference. Verification of the existence of the equipment is required. The department having custody of the capital equipment will have the primary responsibility for this inventory, although the Property Management Department will make itself available to assist in the carrying out of this function.

The Property Management Office will establish a time schedule of all departments for physical inventories. The department should be as specific as possible regarding the disposition information such as, sold, traded, discarded stolen, etc. Any equipment not listed on the worksheet should be added to the list. Each department will receive a thirty day notice of the upcoming inventory. Upon receipt of worksheet(s), the department will have thirty days to complete the inventory and return it with the signature of the department head, departmental chairman or manager to the Property Management Office.

It should be noted that, although primary responsibility for the inventory rests with the department, responsibility for monitoring the successful completion of inventories and maintaining the accuracy of the university property records rests with the Property Management Office.

### **EQUIPMENT TRANSFERS AND DISPOSITIONS OF UNIVERSITY PROPERTY**

The Inventory Release Form (see Appendix), available through University Services, (Printing and Reprographic Services), is used to initiate transfer and disposal procedures of any kind. For University-owned equipment, the form must be signed by the department chairperson or a designated representative. Disposal of equipment refers to the following:

- Donate - to contribute equipment as a gift
- Scrap - to dispose of equipment and receive some value for it as secondhand material
- Junk - to discard equipment with no remaining value
- Sell - to offer equipment for sale

- Trade-In - to trade equipment for new equipment
- Cannibalize - to use parts as replacement in other equipment

Items which are expected to be in demand by University departments are kept in the University's surplus property storage area. Property Management will maintain an up-to-date listing of surplus equipment, which will be available to University departments. Departments in need of equipment should contact Property Management and have their requests placed on the "want list". If the desired equipment is available, a work order must then be filled out, and submitted to the Work Control Center of Campus Facilities and Operations department (CF&O). CF&O charges for the delivery based on the length of time it takes to pick-up and deliver the equipment to the requesting department.

Equipment may be transferred to another department, offered for public sale, donated to a non-profit organization, or junked. To dispose of surplus equipment, material, or supplies, complete an Inventory Release Form (see appendix) listing all items, whether inventoried equipment or not. Send the original of the Release Form to the Property Management Office. The Property Management Office will pick-up small items such as typewriters, or calculators and will delete equipment items from the University Inventory. Larger items such as chairs, desks, files, computers etc. or larger quantities, will be removed by submitting a work order to the Work Control Center. Property shall not be moved from any office without the express consent of the Office of Property Control.

### Storage of Property

The Property Management department has storage available for property that is expected to be in demand by university departments or the university community.

**Criteria:** To determine if an item or items qualify for storage in the Property Management facility, the following criteria must be true. The items are available for:

- Periodic use by the requesting department (such as theatre staging) or,
- Transfer to another department or,
- Offering for public sale or,
- Donation to a non-profit organization.

The director of Property Management, or his/her designee, reserves the right to determine if a department has complied with all the requirements of the storage facility. If the criteria have not been met, storage area will be refused or, in the case of current occupancy, the department will be asked to remove their articles at their expense. Following are the general policies:

- A charge per square foot per month will be charged for storage of materials not being released by departments. The rates and an administrative fee are to be set by the director of Property Management and available online at the University Services' website in the Property Management section.
- Items placed in storage must be:
  - Functional
  - Usable and in working condition
  - Of current value
  - Considered temporary (other than noted above) and will be used within a one year period

- Non-toxic, non-hazardous, non-combustible, non-perishable
- Items stored are the individual department's responsibility.
- A contact name and number must be given to the Property Management office prior to occupying the space.
- Individual keys will access private storage only
- The Property Management office will have proprietary rights to access all storage areas. The department will supply a key to the Property Management Office.
- No personal locks will be allowed. All locks and keys must be university issued.
- Items will be re-evaluated every year against current criteria.

### Donations and Sales of Equipment

Equipment which has little or no value may be donated to a non-profit agency or organization. The Property Management Office must be notified by an Inventory Release Form and a letter of acceptance must be received by the agency or organization receiving the property.

If the equipment retains substantial value and the department wishes to have Property Management sell the equipment, the disposing department must submit an Inventory Release Form. The disposing department may state a "minimum amount acceptable" for resale. A memo stating the minimum acceptable amount and an account to credit any proceeds must accompany the Inventory Release Form. The Property Management Office will then advertise the property's availability at regular intervals, first to the University and then to the public. The Property Management Office will also handle the monetary aspects of the transaction. All proceeds from items sold for \$1,000 or greater, less \$100 or a 10% handling fee, whichever is greater, will be transferred to the requesting department.

Michigan sales tax must be collected on sales to individuals and to organizations not holding a certificate of (tax) exemption.

### Transfer Between Departments

Departmental transfers of equipment may be accomplished by completion of an Inventory Release Form by the department which currently lists the item on its inventory. The department accepting the equipment must also sign the release form and note the new location of the equipment on the form as well. The original of the release form is to be sent to the Property Management Office.

### Lost, Destroyed, or Dismantled Equipment

To delete such an item from the University's inventory, complete an Inventory Release Form and send it to the Property Management Office.

### Theft or Mysterious Disappearance of Equipment

These situations should be reported immediately to OU Police and an Inventory Release Form completed with the original sent to the Property Management Office.

Key control is an important factor in helping to prevent theft of equipment from campus. Department heads should make sure keys are not transferred or passed from one individual to another see Policy #350 - Key Policy for further information. Key holders must report lost or

stolen keys to their department head and the OU Police. The OU Police will send a copy of the report to Property Management. Property Management has the authority to call for a special audit when circumstances dictate.

### Traded-In Equipment

With the approval of the Purchasing Department, equipment may be traded-in against another purchase. The purchase requisition for the new equipment must indicate the OU tag number, description, and manufacturer's serial number for all items being traded. In addition, the requisitioning department must complete an Inventory Release Form and submit it to Property Management.

## **RECORDING OF VALUE OF UNIVERSITY PROPERTY**

The Property Management Office is responsible for recording the value of all property obtained or acquired through any fund source. In recording property value, the following are included: freight charges, custom duty charges, assembly costs, insurance costs for shipments and trade in value. The following items are excluded or subtracted from the value of the property: handling charges, storage charges and maintenance or warranty contract costs. Cash discounts are deducted from the value of property but discounts for timely payment of invoices are not.

## **PERSONAL USE OF PROPERTY**

Use of University material or property in the care and custody of the University, by University employees for personal purposes is not allowed except with the written approval of one of the following: custodial department heads, vice presidents, deans, Principal Investigators or specific contract authorization (in the case of Government Property).

It is to be explicitly understood that the University insurance policy does not provide for coverage for University Property or Government Property once it has physically left the premises of the University unless otherwise specified in the University Policies and Procedures. The liability for said property rests with the individual or individuals responsible for the property.

## **PHYSICAL SECURITY**


Physical security of property is the responsibility of the respective department heads. In order to prevent theft of equipment, high security locks are available through Campus Facilities and Operations. The cost associated with the locks will be charged to the requesting departments. (See Policy #350 in the Policies and Procedures Manual)

Maintenance, repair, calibration, or any other costs related to equipment are the direct responsibility of the custodial department.

Property Management will periodically or upon request send Inventory Equipment Reports to departments. The reports are available in a variety of sorted configurations.

A disposal report is created monthly. It is available in a variety of sort configurations. At fiscal year-end this report is submitted to the Controller.

## APPENDIX



**Oakland**  
UNIVERSITY  
Rochester, Michigan 48309-4400

### INVENTORY RELEASE FORM

**No. 10685**

DATE \_\_\_\_\_

ITEM NO.	QUANTITY	DESCRIPTION	P.O. NO. (IF KNOWN)	ORIGINAL COST	INVENTORY NO.
1					FROM
					TO
2					FROM
					TO
3					FROM
					TO
4					FROM
					TO
5					FROM
					TO
6					FROM
					TO
7					FROM
					TO
8					FROM
					TO

Reason for release (check ONE only):     Cannibalized/Salvage     Junked     Lost/Stolen     Sale (by Transfer)     Sold     Trade-in

APPROVALS:

_____ Releasing Dept., Dept. Head	COPIES: Property Management (Original)
_____ Accepting Dept., Dept. Head	Releasing Dept. (Yellow)
_____ Property Management	Accepting Dept. (Pink)

OU 107 REV. 0-7-07

## Chapter 5: Non-Faculty Research Appointments

### 5.1 Academic Researchers

#### a. Definitions and Roles

Post-doctoral Fellows: A post-doctoral fellow is a temporary research position held by a person who has completed doctoral studies. Post-doctoral fellows have traditionally been dedicated purely to research. The appointee is typically given a title such as Research Associate, or sometimes Research Assistant Professor. Post-doctoral fellows are essential to the scholarly mission of the mentor and host institution, and thus are expected to have the freedom to publish the results of their scholarship.

Research Associate: The title of research associate is used to denote a research position at the post-doctoral level. Research associate is under the supervision of their research supervisor.

Research Assistant: The title of research assistant is used to denote a research position in universities or companies. The title of Research Assistant is used for researchers hold a bachelor or master degree. Research assistants conduct their work under the supervision of their research supervisor.

Oakland University (OU) faculty contract Article IV Academic Titles defines only persons holding an academic title under this Article IV may engage in teaching of credit courses, academic research, or professional library service. Exceptions are graduate students progressing toward a degree who, upon recommendation of the academic unit, and with the approval of Oakland, may teach credit courses. Post-doctoral fellows, research assistants, and research associates also may engage in academic research. No academic titles shall be granted except those set forth in this Article IV. All academic titles shall be granted in accordance with this Agreement, whether or not the person granted the title is a member of the bargaining unit. Any title granted shall be accompanied by a specification of primary appointment.

#### b. General Terms for Academic Researcher Appointments

[Attachment 5a](#) states the general conditions of appointment for all full-time post-doctoral fellows, research associate, and research assistant employed by OU and are an official part of all such offers. Specific conditions (title, salary, etc.) are stated in individual offers of appointment. The appointment is handled by Academic Human Resources Office.

#### c. Guidelines for Hiring Academic Researchers

For detail policies and procedures on hiring academic researchers, please contact University Human Resources (UHR) for appointments less than six months, contact International Student and Scholar Office (ISSO) for foreign students and scholars, and contact Academic Human Resources (AHR) for full time faculty, academic researchers, and H-1B.

Employment of academic researchers is initiated by the department. The following step by step process is a basic guideline to assist department/college/school in hiring full time academic researchers.

- 1) Department creates job description and position requirements.
- 2) Select applicants and interview them.
- 3) Dean or Chair and AHR approve Letter of Offer to candidate for his/her signature. [\(Attachment 5b\)](#)
- 4) Candidate signs acceptance letter.
- 5) Candidate must complete Form I-9 within three working days of the start of work.
- 6) For foreign candidate, please contact him/her to make an appointment for an interview at the Embassy and to let department know the date of visa interview.
- 7) For permanent residents and H-1B holders, please go to the UHR Office for reviewing completeness and accuracy of documents. AHR must review and verify Academic Research Paperwork checklist, but researchers do not need to report to AHR as application completion is at the department level. [\(Attachment 5c\)](#)
- 8) For F-1 and J-1 status holders, candidates should go to ISSO. The ISSO will have a package for each candidate; department needs to pick it up and mail it to the candidate by express mail.
- 9) [Academic Researcher Benefit Summary](#)

**d. Guidelines for Hiring International Academic Researchers**

The proper status to use in bringing international faculty and academic researchers to the university depends in part upon the permanence of the position offered. To determine the appropriate status for each individual, the hiring department/college/school should contact the AHR for specific information. The AHR will consult with the ISSO, or General Counsel, if necessary, to determine the appropriate status and to coordinate the processing of necessary petitions, etc. [\(Attachment 5d\)](#)

**5.2 Visiting Researchers and Scholars**

A visiting scholar is generally a scholar from another institution or organization who visits OU that hosts him/her where he/she is expected to teach (visiting professor), lecture (visiting lecturer), or perform research (visiting researcher or visiting research associate) on a topic the visitor is valued for. The position is often not salaried and typically for one year, though it can be extended.

The purpose of the visiting scholar program is to bring an exceptional senior scholar to OU who can contribute to and enrich the community's intellectual and research endeavors and international collaboration. Hence, in addition to conducting their own research, visitors are often expected to actively participate in a number of institutional activities, such as presenting paper to University's seminar program.

**a. Visiting Scholars Hiring Procedures**



1) Criteria for Appointment

The following are the minimum eligibility for a Visiting Scholar appointed at OU. Individual schools may establish more restrictive eligibility criteria.

- The individual must be visiting from an outside institution or organization.
- The individual must have a doctoral degree or be a recognized expert in his or her field.
- The source of funding for the individual must be identified by the faculty sponsor.

2) Appointment Procedure

The sponsoring department should assure that a candidate for Visiting Scholar meets the criteria listed above. OU has established policies and procedures for visiting faculty appointment procedures.

Oakland University Administrative Policies and Procedures 750 ([Attachment 5e](#))

**b. Guidelines for Hiring International Faculty and Visiting Scholars**

The proper status to use in bringing international faculty and visiting academic researchers/scholars to the university depends in part upon the permanence of the position offered. To determine the appropriate status for each individual, the hiring department/college/school should contact the AHR for specific information. The AHR will consult with the ISSO, if necessary, to determine the appropriate status and to coordinate the processing of necessary petitions, etc.

**Visa Requests for Foreign Visiting Scholars**

When OU invites a foreign visiting scholar, a J-1 visa is the appropriate visa for the visitor. The Application for Visiting Scholars and Professors DS-2019 Form should be completed by sponsored faculty. The sponsored faculty must assure that foreign scholars receive their DS-2019 well before departure from their home country, and that they understand that they must use the DS-2019 to apply for a J-1 visa at a U.S. Consulate.

**c. Benefits Summary**

This web link [http://www4.oakland.edu/upload/docs/UHR/Visiting\\_Faculty.pdf](http://www4.oakland.edu/upload/docs/UHR/Visiting_Faculty.pdf) intended to provide an overview of benefits for Visiting Faculty employees at OU. Health care directories are available in the Benefit and Compensation Services Office.

**5.3 Appointment of Consultants**

**a. Independent Contractor Hiring Procedures**

Independent contractors perform compensated work for OU, but they are not considered employees for purposes of payroll taxes, workers' compensation, unemployment compensation, fringe benefits, or for any other purpose. Oakland University Administrative Policies and Procedures # 262 provides guidelines for determining whether individual providing services to OU should be classified as an independent contract.

Oakland University Administrative Policies and Procedures # 235 includes Independent Contracting Services Agreement form, Invoice for Independent Contracting template, payment

procedures, patents & copyrights, technical records & reports, confidentiality, conflict of interest, non-resident alien paper work requirements, etc.

Independent contractor may also use its own service agreement. However, agreement presented by the independent contractor has to be reviewed by OU General Counsel before service starts.

**b. Personal Services: Independent Contractor vs. Employee Status**

Under federal law, a worker is either an employee or an independent contractor. An employer-employee relationship exists when OU has a right to supervise and control the service performance and result. An independent contractor relationship exists when an individual or organization is independent of OU's supervision and control with respect to the manner of performance. The determination criteria are stated in OU policy # 262.

Quick Reference Chart

<b>Independent Contractor Status</b>	<b>Employee Status</b>
Not providing on-going services	On-going services
Not active OU employee	Active OU employee
Work engaged with 3 consecutive days	Work engaged more than 2 weeks
	Applied music/nursing instructor
	Special lecturer, lecturer

**c. Terms and Conditions of Federal Consultants**

- 1) In NIH Grants Policy Statement (12/03), Part II: Subpart A: General – file 3 of 5. Consultant Services are allowable cost. It states: A consultant is an individual retained to provide professional advice or services for a fee but usually not as an employee of the requiring organization. The term “consultant” also includes a firm that provides paid professional advice or services. Grantees must have written policies governing their use of consultants that are consistently applied regardless of the source of support. Such policies should include the conditions for paying consulting fees. The general circumstances of allowability of these costs, which may include fees and travel and subsistence costs, are addressed in the applicable cost principles under “professional services costs.”

In unusual situations, a person may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee as long as those separate services are not related to the same project and are not charged to the same project. For example, consulting fees that are paid by an educational institution to a salaried faculty member as extra compensation above that individual's base salary are allowable, provided the consultation is across departmental lines or involves a separate or remote operation and the work performed by the consultant is in addition to his or her regular departmental workload.

[http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPs\\_Part6.htm](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part6.htm)

- 2) In NSF Award & Admin Guide Chapter V – Allowability of Cost, B. Direct Costs, 6. Consultant Services, item a. Outside Consultants, b. Intra-university Consulting. It states,
- a. Outside Consultants
- (i) Grantees normally are expected to utilize the services of their own officers or employees to the maximum extent in managing and performing the activities supported by NSF grants. Where it is necessary for a grantee to enter into a subaward for the services of persons who are not its officers or employees, it is expected to do so in accordance with written organizational standards which provide for consideration of the factors outlined in the governing cost principles.
  - (ii) Costs of professional and consultant services rendered by persons who are members of a particular profession or possess a special skill and who are not officers or employees of the performing organization are allowable when reasonable in relation to the services rendered. Payment for consultant services should be comparable to the normal or customary fees charged and received by the consultant for comparable services, especially on non-government contracts and grants. For all funds awarded prior to March 15, 2006, payment for a consultant's services may not exceed the daily equivalent of the then current maximum rate paid to an Executive Schedule Level IV Federal employee (exclusive of indirect cost, travel, per diem, clerical services, fringe benefits and supplies).
  - (iii) In determining the allowability of costs in a particular case, no single factor or any special combination of factors is necessarily determinative. However, the following factors, among others, are relevant:
    - (a) the nature and scope of the service rendered in relation to the service required;
    - (b) the necessity of issuing a subaward for the service considering the organization's capability in the particular area;
    - (c) the past pattern of such costs, particularly in the years prior to the award of government contracts and grants;
    - (d) the impact of government contracts and grants on the organization's total activity (e.g., what new problems have arisen);
    - (e) whether the proportion of government work to the organization's total activity is such as to influence the organization in favor of incurring the cost, particularly where the services rendered are not of a continuing nature and have little relationship to work under government contracts and grants;
    - (f) whether the service can be performed more economically by employment rather than by consulting;
    - (g) the qualifications of the individual or concern rendering the service and the normal/customary fees charged and received by the individual for comparable services, especially on non-government contracts and grants; and
    - (h) adequacy of the contractual agreement for the service (e.g., description of the service, estimate of time required, rate of compensation and termination provisions).
  - (iv) In addition, retainer fees to be allowable must be supported by evidence of bona fide services available or rendered.

- (v) Costs of legal, accounting and consulting services and related costs incurred in connection with organization and reorganization, defense of antitrust suits and the prosecution of claims against the government are unallowable. Costs of legal, accounting and consulting services and related costs incurred in connection with patent infringement litigation are unallowable unless otherwise provided for in the grant.
- (vi) Grantees may hire consultants not identified in the grant proposal or award, provided:
  - (a) it is in accordance with written organizational standards;
  - (b) grant funds are reallocated in accordance with the grantee's policies which are consistent with the governing cost principles; and
  - (c) it is within the limits of the grant funding.

#### **d. Intra-University Consulting**

Since intra-university consulting is assumed to be undertaken as a university obligation requiring no compensation in addition to full-time salary, the principles summarized in AAG Chapter V.B.1, also apply to those who function as consultants or otherwise contribute to a project conducted by another faculty member of the same institution. However, in unusual cases where consultation is across departmental lines or involves a separate or remote operation, and the work performed by the consultant is in addition to his/her regular appointment, any charges for such work representing extra compensation above the salary are allowable if consistent with established university policy and the applicable cost principles.

<http://www.nsf.gov/pubs/policydocs/papp/aag07140.pdf>

### **5.4 Graduate Student Assistantship**

A graduate student is an individual who is admitted and enrolled in a master degree or doctoral degree program in good academic standing in graduate studies at OU. The graduate studies programs provide graduate student assistantships to graduate students. Those assistantships are directly related to the graduate studies or research studies of student's graduate degrees.

#### **a. Graduate Assistantship Policy Guidelines**

The Office of Graduate Study (OGS) has developed Graduate Assistantship Policy Guidelines to provide general policies and regulations that apply to graduate degree programs at OU. OU provides graduate assistantships to graduate teaching assistants and graduate research assistants.

##### Minimum Criteria for Appointment

- The student must be a master or doctoral degree seeking student in good academic standing
- The student is admitted to and enrolled in a degree program
- International students must have the appropriate student status with USCIS.

##### Appointment Procedure

A graduate student who wishes to apply for a Graduate Assistantship should request an application form directly from the department or academic unit in which he or she is interested in. Step by step application process is referred to Graduate Assistantship Policy Guidelines – How to Apply for a Graduate Assistantship.

- 1) The applicant must complete an application for Graduate Assistantship Award form.
- 2) The applicant must submit the application form directly to the academic unit or department in which she or he is requesting an appointment. The applicant should not submit the application form to the Office of Graduate Study.
- 3) Before an applicant can be awarded a Graduate Assistantship, the applicant must be admitted to a graduate degree program.
- 4) The letter of offer and Graduate Assistant Agreement will come directly from the academic unit or department (except with an international applicant).
- 5) To accept a Graduate Assistantship appointment, the applicant must sign, date and return the Graduate Assistant Agreement to the academic unit or department.
- 6) A student who has been awarded a Graduate Assistantship will receive the award only for the duration stated in the Graduate Assistant Agreement.

**b. Graduate Assistant Agreement**

The Graduate Assistant Agreement should be approved by the Principal Investigator and Chairperson/Associate Dean. The student must sign to accept the terms and conditions of this Agreement. The Agreement and letter of offer should be submitted from academic unit or department (except international applicant) to the Office of Graduate Study.

**5.5 Tuition Support for Graduate Research Assistants**

On September 1, 2008, OU's Office of Grants Contracts and Sponsored Research (GCSR) has developed a new tuition incentive program for graduate research assistants (GRA). The new tuition incentive program expands the tuition support not only for established principal investigators but also for new principal investigators and junior faculty.

Criteria for the Graduate Research Assistant Tuition (GReAT) support are as follows:

- 1) This Graduate Research Assistant Tuition (GReAT) Program is to supplement tuition support to **full-time ( $\geq 8$  credit hours/semester per OU policy)** graduate research assistant (**GRA**).
- 2) The faculty advisor/mentor or unit head must provide evidence that the GRA is, or will be, receiving stipend support to conduct research during the period of GReAT support.
- 3) Teaching Assistants (TAs) and recipients of any other scholarships are **not** qualified for GReAT.
- 4) The GReAT Program allows for up to a total of 32 credit hours per student, up to 16 credit hours per academic year for a maximum of two years. [\(Attachment 5f\)](#)

## **5.6 Research Opportunities for Faculty and Students**

The University Research Committee (URC) at OU offers research awards to selected faculty and students every year. Types of awards include faculty research award, fellowship award, faculty excellent in research award, student research award, student travel award, and conference grant. Faculty and students must submit research proposal for committee review and approval.

Awards administered by GCSR include University Research Committee Awards, Provost's Graduate and Undergraduate Student Research Awards, Provost's Multidisciplinary Undergraduate Research Award, Chrysler Undergraduate Student Research Award, and OU-Beaumont Multidisciplinary Research Award.

Awards handled by other department or units include Automotive Research Experience for Undergraduates (REU), Summer Undergraduate Program in Eye Research, UNCORE summer Engineering Computer Research, Department of Chemistry Research Opportunities, Department of Physics Research Opportunities, etc.

[www.oakland.edu/research](http://www.oakland.edu/research)



## GENERAL TERMS FOR ACADEMIC RESEARCHER APPOINTMENTS

This document states the general conditions of appointment for all full-time faculty employed by OU and is an official part of all such offers. Specific conditions (title, salary, etc.) are stated in individual offers of appointment.

- **New Employees**

For appointees not currently in the University payroll system, enclosed are one or more of the following forms, which must be completed and returned: Federal and Michigan withholding exemption forms, a personnel information sheet, a state employee's oath card, and an employment eligibility verification form. Forms previously completed by virtue of a prior appointment are not enclosed.

- **Loyalty Oath**

The loyalty oath is required of citizens of the United States for employment at any state institution of Michigan. If you accept this offer, please sign the enclosed card (it is not necessary to sign the card before a notary public). Citizens of foreign countries are not required to sign this oath, but are requested to complete the oath card, indicating the country of citizenship in the space reserved for the signature.

- **FERPA (Family Educational Rights & Privacy Act)**

OU employees are to understand and comply with the terms of the Family Educational Rights & Privacy Act, especially when using Oakland's information systems. A copy of this act is located at the following website:  
<http://www2.oakland.edu/audit/POLCY1130.HTM>

- **Use of University Information Technology Services**

OU employees are to understand and comply with the terms of the Use of University Information Technology Services policy, especially when using Oakland's information systems. A copy of this policy is located at the following website:  
<http://www3.oakland.edu/oakland/frames.asp?main=http://www2.oakland.edu/audit>

- **Immigration and Naturalization Service Status**

This offer is contingent upon having appropriate status with United States Immigration and Naturalization Service.

- **Employment Eligibility Verification Form**

The Employment Eligibility Verification Form (I-9 form) for all new employees is a requirement of the Federal Immigration Reform and Control Act of 1986. If you accept this offer, original documents listed on the eligibility verification must be presented, and the form must be completed and signed by an agent of OU within three working days after the start of the term of appointment. The School or Department secretary is an authorized agent of the University.

- **Social Security Card**

The Social Security Administration requires that we have a copy of your Social Security card on file within three (3) days of date of hire. If you do not have a Social Security

card, one must be applied for and the receipt submitted to the school or department secretary. The new card must be on file within 90 days in order to be in compliance with federal law.

- **Sexual Harassment Training**

Employees of OU are required to complete and pass sexual harassment training within the first three days of their employment. The training is available online at <http://training.newmedialearning.com/psh/oakland/>.

- **Transcripts**

This appointment requires that a transcript showing award of the doctoral degree be provided to Oakland at the time of hire.

- **Benefits Enrollment**

To obtain coverage in benefit programs, you must complete the enrollment forms no later than 60 days following your employment date. For further information, please contact Benefit Services at (248) 370-4207.

- **Physical Examination**

Your employment is subject to satisfactory completion of a physical examination. The University will pay a reasonable cost toward a physical examination by a personal physician (or arrangements are available through OU's Graham Health Center to have the examination performed at no cost to you). You are cautioned not to terminate any present contracts that you may have until your physical examination has been approved by our medical services. The enclosed health examination form should be completed by your physician, should you choose this option, and be mailed to:

Graham Health Center  
Oakland University  
Rochester, Michigan 48309-4401

The examining doctor should send a statement of service to:

<<School or Department>>  
Oakland University  
Rochester, Michigan 48309

- **Handicapper Accommodations**

OU is a non-discriminatory, affirmative action employer. In accordance with the Michigan Handicapper Civil Rights Act, handicappers who require accommodation to perform the duties of their position must notify their supervisors in writing of this need within 182 days of receipt of this notice or within 182 days of knowledge of the need for such accommodation.

PLEASE SIGN THE ORIGINAL OF THIS DOCUMENT WHERE INDICATED BELOW AND RETURN IT TO THE DEAN'S OFFICE, ALONG WITH THE SIGNED ACCEPTANCE OF THE ACCOMPANYING LETTER OF OFFER AND ANY EMPLOYMENT FORMS WHICH WERE ENCLOSED.

ACCEPTED: \_\_\_\_\_ DATE: \_\_\_\_\_



**SAMPLE LETTER OF OFFER TO AN ACADEMIC RESEARCHER**

Please note: Those sentences in bold print should be added only if they apply to the candidate. Underscored portions are for explanation purposes only; do not include as part of the letter.

Date

Name  
Address

Dear \_\_\_\_\_:

It is my pleasure to extend to you an invitation to join the OU community. Accordingly, I make you the offer of           Academic Trainee

Research Assistant of  
Research Associate of  
Assistant Researcher of  
Associate Researcher of  
Researcher of

for the period \_\_\_\_\_ to \_\_\_\_\_ with a salary for the period of \$\_\_\_\_\_ **(per month/per year)**. This is a grant-funded position and is contingent upon **(give explanation for funding)**. Please note that this offer of employment is not for a tenure track position.

If these terms are acceptable, please return your written acceptance, a signed original of the enclosed General Terms, and all employment forms according to the enclosed instructions. **(Alternate to the preceding sentence: This offer will remain open until \_\_\_\_\_ and I hope that I will receive your acceptance by then.)** I await your reply and hope that you accept our offer. If you have any questions, please do not hesitate to write.

Sincerely,

**(Dean of the School or College)**

Enclosures:   General Terms  
                  Federal/Michigan Withholding Exemption Certificate **(at initial offer only)**  
                  State Employees Oath Card **(at initial offer only)**  
                  Employment Eligibility (I-9) Form  
                  Health Examination Report **(at initial offer only)**  
                  Personnel Information Sheet **(at initial offer only)**  
                  Copy of Letter  
                  Faculty Benefit and Compensation Information Sheet **(at initial offer only)**

Cc:    Department Chairperson  
      Provost **(This copy should be held and sent to the Provost after the candidate has accepted the position.)**

## ACADEMIC RESEARCHER PAPERWORK CHECKLIST

NAME: \_\_\_\_\_

SCHOOL: \_\_\_\_\_

DEPT: \_\_\_\_\_

EMPLOYEE CLASS:      RR  
                                YY

TYPE OF FORM	CHECK IF RECEIVED	DEPT. THAT SHOULD RECEIVE COMPLETED FORM
Signed Offer Letter		Academic Affairs (AA)
Signed Acceptance Letter		AA
Signed General Terms		AA
Employment Eligibility (I9) Form		AA
Social Security Card Copy		AA
Curriculum Vitae		AA
Transcript		AA
Personnel Information Form		AA
Health Exam Card		AA
State Oath Card		AA
Fed/St. Tax Withholding Forms		PAYROLL

## **GUIDELINES FOR HIRING INTERNATIONAL FACULTY**

**Office of the Vice President for Academic Affairs and Provost  
Oakland University**

### **INTRODUCTION**

These guidelines are intended to provide assistance to individuals and departments in the process of hiring or renewing status of faculty and academic researchers who are not citizens or permanent residents of the United States. Faculty members include individuals with appointments as regular full-time faculty, research professors, full-time adjunct faculty, visiting faculty, special lecturers and lecturers. Academic researchers falling under these guidelines include individuals with appointments as researcher, associate researcher, assistant researcher, research associate, research assistant and academic trainee.

University appointments are subject to the Federal Government requirement that non-U.S. workers have valid status while employed. The General Terms sections of all employment offers to faculty and academic researchers must include standard language sections on United States Citizenship and Immigration Services Status and the Employment Eligibility Verification Form (Form I-9). All employment offers must be signed by the dean or director of the academic unit. The dean's/director's office has access to the standard employment letters of offer and general terms. Following acceptance of employment at the university and within three days of the start of employment, any new employee must complete the form I-9, Employment Eligibility Verification, to verify that their work authorization status is in order.

Occasionally, departments wish to utilize the expertise of international visitors for very short-term engagements, such as continuing education courses or guest lectures. The process for reimbursing such individuals for incidental expenses and/or to provide an honorarium is described below under the heading of Guidelines for Non-Employee Visitors.

### **EMPLOYMENT AT OAKLAND UNIVERSITY**

The proper status to use in bringing international faculty and academic researchers to the university depends in part upon the permanence of the position offered. To determine the appropriate status for each individual, the hiring department/college/school should contact the Academic Affairs Office for specific information. The Academic Affairs Office will consult with the International Students and Scholars Office, if necessary, to determine the appropriate status and to coordinate the processing of necessary petitions, etc.

### **TEMPORARY APPOINTMENTS**

The following non-immigrant classifications are most commonly used for faculty or academic researcher temporary appointments:

- F-1 (OPT) – Academic Students, authorized for optional practical training
- H-1B – Specialty Occupations
- J-1 – Exchange Visitors
- TN – Canadian/Mexican Professional

Non-immigrant status (F, J, TN or H) is appropriate for visiting and temporary faculty/academic researchers who are appointed for fixed periods outside the tenure system. The Academic Affairs Office will recommend the appropriate status to the hiring unit based upon the unit's objectives and the applicant's individual circumstances. For H status, the Academic Affairs Office, in consultation with the appropriate department, college and/or school, will process the necessary paperwork or will sign off on any such paperwork prepared by a third party (e.g., immigration attorney). For J status, the Office of International Students and Scholars will be consulted and authorized to process the necessary documents. For F-1 (OPT) status, the educational institution that enrolls the non-immigrant (someone just completing a graduate program, for example) would process the necessary documents.

### **TENURE-TRACK AND OTHER CONTINUING APPOINTMENTS**

Immigrant status or permanent residency is most appropriate for faculty appointed in the tenure system or academic researchers appointed in a continuing appointment category. Until permanent residency can be obtained, an H-1B non-immigrant status may be approved by the United States Citizenship and Immigration Services (USCIS) for a maximum period of six years (initial maximum is three years with extensions available). USCIS regulations allow for dual intent for both the H-1B petitioner and employee. This means an employee can hold H-1B status and begin the permanent resident process without restricting their ability to travel outside the U.S. or continue to work. J-1 exchange visitor status is not appropriate for tenure system or other continuing appointments.

### **TENURED APPOINTMENTS**

Tenured appointments may be filled by an individual who has immigrant status or permanent residency, but not by a non-immigrant. If an appointment confers immediate tenure (e.g., associate professor with tenure or full professor), the individual must obtain an immigrant status before such an offer is finalized, or the appointment is effective.

### **GUIDELINES RELATIVE TO SPECIFIC NON-IMMIGRANT STATUS TYPES**

#### **F-1 Student Status**

Faculty may begin employment at the university while in status as a student, approved for optional practical training (F-1, OPT) while completing or following completion of a degree. Such status is processed by the university in which the faculty member is a student and is valid for up to one year maximum. OU would, therefore, not be involved in processing the petition necessary to obtain such status. However, if the faculty member's appointment extends beyond one year, Oakland would need to begin the process of petitioning for a new status type (most likely H-1B status) in order to maintain the faculty member's employment eligibility into the future.

Academic researchers may also be hired with the F-1, OPT status if the position at Oakland can be considered training in the field of the researcher's course of study.

Any F-1 petition that OU may be involved with, such as for a postdoctoral research student, would be processed through the Office of International Students and Scholars.

#### **J-1 Exchange Visitor Status**

Exchange visitor status may be most appropriate for temporary faculty or academic researcher appointments. The intent of the enabling legislation for this non-immigrant status is exchange. The assumption is that the non-immigrant is temporarily in the U.S. and expects to return home. The United States Department of State assigns exchange visitor program numbers to U.S. government agencies, colleges, universities, and other legitimate sponsors. Exchange visitors

who receive any funding from the U.S. government, their home government, or are under their country's skills list are subject to a two-year home country physical presence requirement (i.e., they must leave the U.S. and comply with the two-year home stay) before they can apply for adjustment of status to an immigrant, or change to another non-immigrant status.

Processing of exchange visitor (J-1) status for faculty and academic researchers is referred to the Office of International Students and Scholars.

### **H-1B Non-immigrant Specialty Occupation Status**

The H-1B is the typical status sought for faculty or academic researchers who are hired in positions that may become permanent, such as tenure-track faculty. The university may have a "dual intent" in hiring an individual, first temporarily and later permanently, if approved for immigrant status. The maximum period of time an individual may remain in the U.S. in H-1B status is six years (initial maximum of three years with the possibility to extend for up to three additional years).

The General Council Office will process H-1B status petitions in coordination with the appropriate department, college and/or school. Petition processing costs will be the responsibility of the department. Alternatively, with the approval of the Academic Affairs Office, an immigration attorney may be contracted to prepare the petition and accompany documents, but a representative of the Academic Affairs Office will sign the I-129 petition (Petition for a Non-immigrant Worker) on behalf of the university. In this case, the attorney fees will be the responsibility of the (potential) employee or the department.

When signing an I-129 petition for a non-immigrant worker, the university is certifying to the following: 1) the validity of the information submitted relating to the university as well as the non-immigrant; 2) the terms of the labor condition application that is obtained as part of the petition process, which include attestations concerning the prevailing wage of the position, working conditions, possible labor disputes, and notice of filing of the petition; and 3) that the employer will be liable for the reasonable costs of return transportation of the alien abroad if the alien is dismissed from employment before the end of the period of authorized stay.

### **GUIDELINES FOR APPLICATION FOR IMMIGRANT STATUS**

Obtaining immigrant status is generally a three-step process: 1) submission of an Application for Permanent Employment Certification, ETA Form 9089, to the U.S. Department of Labor; 2) submission of an Immigrant Petition for Alien Worker, Form I-140, to the Bureau of Citizenship and Immigration Services; and 3) submission of an Application for Permanent Residence, Form I-485, to the Bureau of Citizenship and Immigration Services or a U.S. Consulate. The preparation and filing for immigrant status is the joint responsibility of the hiring unit and the employee.

Petitions for immigrant status should be submitted only for individuals for whom OU can show a documented long-term interest. This specifically excludes post-doctoral fellows. Teaching and research faculty in tenure track positions constitute the vast majority of immigrant petitions.

A person who has engaged in unauthorized employment or who has been out of status at any time while in the U.S. may not adjust to an immigrant within the U.S.

Faculty or academic researchers who are seeking immigrant status are advised to seek the assistance of an immigration attorney and they are responsible for covering all costs associated with this process. However, since the university is closely involved with certifying the forms and

associated documents that are involved at all three steps as described above, the university is willing to assist any individual who assumes responsibility for undertaking the immigration process on their own, with the understanding that such assistance can only be offered if the appropriate representative of the Academic Affairs Office is available at the time, and no complications are anticipated that might require specialized legal handling.

#### **GUIDELINES FOR NON-EMPLOYEE VISITORS**

B-1 Visitor status may be appropriate for international visitors who provide very short-term service to the university, perhaps in the role of a continuing education instructor or a guest lecturer. Such individuals are not processed as employees and not placed on the university payroll. As long as the services of such individuals do not exceed nine days at OU (and perform services at no more than five institutions in the U.S. within a six-month period), such people can be reimbursed for incidental expenses (travel and lodging) and provided with an honorarium appropriate for their services rendered.

The Academic Affairs Office should be contacted in advance to insure that a potential candidate would qualify for visitor status. If so, it is advisable to send a letter of invitation to the international visitor so that they can present this documentation and request B-1 status at the time of entry into the U.S.

#### **INSTRUCTIONS AND PROCEDURES FOR DEPARTMENTS/COLLEGE/SCHOOLS**

Questions regarding the hiring of international faculty and academic researchers (individuals who are not U.S. citizens or permanent residents) should be directed to the Academic Affairs Office. Immediately upon hiring of a foreign national, an International Employee Data Sheet (attachment 6) should be submitted to the Academic Affairs Office in order to insure that the new employee will be eligible to work on the begin date specified in the letter of offer.

INTERNATIONAL EMPLOYEE DATA SHEET  
for the purpose of employing  
Faculty and Academic Researchers  
at Oakland University

To be Completed by Potential Employee:

**SECTION I**

Family Name (Last Name)                      Given Name (First Name)                      Middle Name:

All Other Names Used (include maiden name and names from all previous marriages)

Gender:        \_\_\_\_\_ Male                      \_\_\_\_\_ Female

Date of Birth (mm/dd/yyyy)                      U.S. Social Security Number (if any)                      A# (if any)

Country of Birth                      City of Birth                      Country of Citizenship

Country of Legal Permanent Residence                      E-mail Address

**SECTION 2A**

If in the United States, complete the following:

Date of Last Arrival (mm/dd/yyyy)                      I-94#                      Current non-immigrant status

Date Status Expires (mm/dd/yyyy)                      Passport #                      Date Passport Issued (mm/dd/yyyy)

Date Passport Expires (mm/dd/yyyy)                      Current U.S. Address                      Phone Number

Brief History of Visa Status in the U.S.

## **INTERNATIONAL EMPLOYEE DATA SHEET**

for the purpose of employing  
Faculty and Academic Researchers  
at Oakland University

This information sheet must be completed and returned to the Office of the Senior Vice President for Academic Affairs and Provost (room 205 Wilson Hall) immediately upon hiring of a faculty member or academic researchers who is not a U.S. citizen or permanent resident. This information is necessary to determine the appropriate non-immigrant status that must be obtained prior to the employment of the individual, and to collect all necessary information that may be needed in processing the non-immigrant petitions. Those individuals who are being offered positions that may become permanent (e.g., regular full-time faculty) will most likely be processed for H-1B status and all of the information requested below will be necessary. For individuals for visiting scholar or postdoctoral research positions, J-1 status may be most appropriate. In this case, the Office of International Students and Scholars will be consulted to complete the processing of necessary petitions and that office will be provided with the information below.

### **To be completed by hiring department/college/school:**

Name of (potential) employee (Last, First, Middle):

Position title:

Salary:

Starting date and term of employment (if any):

Department/College/School:

Department/College/School address:

Department/College/School contact person:

Phone number:

Fax number:

E-mail address:

Brief non-technical position description:

### **Department Authorization**

It is understood that any willful violation connected with providing inaccurate information for the non-immigrant petition or labor condition application (if any) may incur a severe penalty that has long-range impact on OU's ability to employ internationals.

If an international employee holding an H-1B status is dismissed before the end of the authorized period of H-1B employment, it is understood that the department will be responsible for paying the reasonable costs of return transportation of the employee to the employee's last



place of foreign residence. The exception is when the employee voluntarily terminates/resigns his/her employment.

Name of Department Chairperson/College or School Dean/ERI Director:

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

References:

<http://www.oakland.edu/>

[http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part6.htm](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm)

<http://www.nsf.gov/pubs/policydocs/papp/aag07140.pdf>



# Oakland University

## Administrative Policies and Procedures

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**NUMBER:** 750

**SUBJECT:** OAKLAND UNIVERSITY FACULTY HIRING PROCEDURES

**AUTHORIZING BODY:** BOARD OF TRUSTEES

**RESPONSIBLE OFFICE:** VICE PRESIDENT FOR ACADEMIC AFFAIRS

**DATE ISSUED:** OCTOBER, 1993

**LAST UPDATE:** JUNE, 1996

**RATIONALE:** OU has established policies of nondiscrimination and affirmative action for all hiring and employment decisions.

**POLICY:**

**I. EQUAL OPPORTUNITY POLICY**

The Equal Opportunity Policy, approved by the OU Board of Trustees on May 21, 1981; and amended by the Board of Trustees on June 8, 1995, states:

*OU reaffirms its unwavering commitment to equality of opportunity for all persons. In a society that relies on an informed, educated citizenry, no one should be denied the opportunity to attain his or her fullest potential. The University shall strive to build a community that welcomes and honors all persons and that provides equal opportunity in education and employment. It is the policy of OU that there shall be no unlawful discrimination against any person on the basis of race, sex, sexual orientation, age, height, weight, handicap, color, religion, creed, national origin or ancestry, marital status, familial status or veteran status. The University shall affirmatively follow the provisions of applicable State and Federal anti-discrimination legislation in all of its activities in this area and so reaffirms its policy at this time. To the extent that this policy conflicts with first amendment or other legal rights of members of the university community, such other relevant legal provisions shall control. Furthermore, this policy shall not be interpreted to modify eligibility criteria for student and employment benefits or modify the legal definition of the terms "spouse" or "dependent."*

The Affirmative Action Policy, approved by the Board on May 10, 1989, states:

*In order to accomplish the goals set forth in the institution's role and mission statement, it is essential that OU's work force be appropriately representative of all racial and ethnic groups and of both genders. Accordingly, the University establishes an Affirmative Action Plan for the purpose of elimination and/or avoiding racial and sexual imbalances in traditionally segregated job categories. The goal of the Plan shall be to achieve within the University community a work force that is reasonably representative of minorities and women as measured by the race and sex mix of persons with the requisite skills within the reasonable employee recruiting area of the University. Once the goal is reached, a plan will no longer be necessary or appropriate, since any significant imbalances will have been eliminated. The University's commitment to equal opportunity shall, however, continue undiminished.*

*The Plan shall not create "quotas" that must be met, but rather "goals" for minorities and women that promote consideration of affirmative action concerns when establishing and filling positions.*

*The University administration shall develop and implement a plan in conformance with the policy enunciated above. It is expected that goals and procedures contained within the Plan will change periodically in accordance with conditions and experience. . .*

*All persons with hiring responsibilities have the obligation to ensure compliance with the University's equal opportunity and affirmative action policies and the Affirmative Action Plan and its associated hiring procedures.*

Using these Board approved statements as a framework, the faculty hiring procedures described in this document have been developed. It is designed to assist each academic department to develop a faculty representative of the population of qualified professionals in the discipline. It is also meant to support the required analyses of recruitment and hiring patterns and to assure consistent policy implementation.

## **II. SCOPE**

This procedure applies to the appointment of all tenure track and visiting faculty positions. Deans, academic administrators, and non-instructional staff

are covered by separate, comparable procedures. Persons hiring part-time faculty are expected to adhere to the Equal Opportunity and Affirmative Action policies. It is generally understood that those appointments may have different hiring practices. A discussion of part-time appointments can be found in Section VIII.

## **III. OFFICE OF EQUAL OPPORTUNITY**

The Office of Equal Opportunity (OEO) assists in institutional compliance concerning equal opportunity. Therefore, the Director of the OEO must be consulted in the development of position descriptions, advertisements, recruitment plans, and selection criteria. The director is available to advise on selection criteria and provide other assistance during the screening process.

#### IV. PROCEDURE

1. Deans, the Director of the Eye Research Institute (ERI) and chairs anticipating open positions as well as potential search committee members will be provided with recruitment training.
2. Vice President for Academic Affairs authorizes filling position.
3. Department chairperson appoints the Search Committee with the approval of the Dean. Where the college, the institute, the library or a school does not maintain separate departments, the Dean or Director of the ERI shall appoint the Search Committee. A check list will be provided to Deans or Director of the ERI to assist in identifying issues relevant to the search.
4. Search Committee:
  1. Reviews provided assessment checklist to organize search effectively.
  2. Contacts Office of Equal Opportunity for forms and further information relative to implementation of this procedure.
  3. Develops proposed minimum qualifications and a position description subject to administrative approval as provided on the Faculty Recruitment Record.
  4. Prepares advertisement and posting.
  5. Develops selection criteria.
  6. Develops recruitment plan.
  7. Completes section A of Faculty Recruitment Record and identifies initial sources for Section B.
5. Dean or Director of ERI reviews section A and proposed sources in Section B of Faculty Recruitment Record.
6. After approval has been received from the Dean or Director of ERI, the Search Committee, through departmental or school channels:
  1. Sends posting to AAUP, Office of Equal Opportunity and the Office of the Vice President for Academic Affairs.
  2. Places advertisement in external publications and makes external contacts.
  3. Receives candidate materials and sends acknowledgments.
  4. Provides the Office of Equal Opportunity with the names and contact addresses of all candidates meeting minimum qualifications. The OEO will then send these individuals affirmative action inquiry cards.
7. Office of Equal Opportunity provides Search Committee with summary of responses to affirmative action inquiry cards, and any other information relative to the availability of members of protected groups for the position on a timely basis. The OEO may recommend to the Search Committee continuation of search for qualified candidates when the initial pool of candidates does not provide a representative group of candidates.
8. Search Committee screens candidates to arrive at a proposed group of finalists, updates section B and completes section C of Faculty Recruitment Record and sends it to the Dean, Director of the ERI or Chairperson.
9. Chairperson of Department, Dean or Director of ERI, Director of Office of Equal Opportunity and Office of the Vice President of Academic Affairs approve section C. The Office of the Vice President for Academic Affairs may require a continuation of the search for qualified candidates.
10. Finalists are interviewed and otherwise additionally screened by the hiring unit and an employment recommendation is formulated. Hiring unit completes section D of the Faculty Recruitment Record and a written narrative (see Appendix A).
11. Chairperson of Department, Dean or Director of ERI, Director of Office of Equal Opportunity, and the Office of the Vice President for Academic Affairs approve section

- D. The Office of the Vice President for Academic Affairs will review all hiring recommendations with the OEO prior to rendering a decision.
12. Dean or Director of the ERI makes offer of employment to an approved candidate subject to Board approval for tenure track positions.

## **V. GUIDELINES FOR IMPLEMENTING PROCEDURE**

### Introduction

These guidelines expand upon the procedures in the appointment process for faculty. OU has developed these procedures in an attempt to provide equal employment opportunity and to recruit a staff of the highest quality.

In contemporary society, faculties which include representative numbers of women, persons with disabilities and minority groups can provide a more effective academic environment. An integrated faculty supplies important role models for students of all groups and may be more sensitive to the special problems of minority students.

### Search Committee

When faculty positions are to be filled, the department chairperson will appoint a Search Committee. It is recommended that female, minority and persons with disabilities be included wherever possible.

The Search Committee shall develop the position description, which shall include the minimum qualifications for the position. The Federal Guidelines for Employee Selection Criteria require that all qualifications used to screen applicants be directly related to the position being filled. Those qualifications must all be necessary to perform the work successfully and be measurable to demonstrable. Every reasonable effort shall be made to avoid using standards which are not necessary to perform the responsibilities of the position and which might have the effect of excluding protected groups.

An advertisement shall be developed by the Search Committee. It must include the minimum qualifications for the position, and a statement that OU is an equal opportunity and affirmative action institution. The Dean or Director of ERIs approval of the position description, minimum qualifications and the advertisement is required prior to dissemination of the advertisement.

The Search Committee shall also prepare a recruitment plan. A good faith effort must be made to attract female, minority and disabled applicants by contacting organizations and publishers which serve these groups, as well as individuals who may know of qualified candidates. This effort shall be documented on section B of the Faculty Recruitment Record. The recruitment plan can be expanded during the search.

A position should be advertised in appropriate publications at least two months in advance of the closing date for accepting applications. A closing date should be included in the advertisement; the following language is suggested: "In order to ensure consideration, applications must be received by (date)."

The Office of Equal Opportunity must be consulted in development of job descriptions, advertisements and recruiting plans.

## Screening Procedures

The Search Committee shall develop selection criteria, subject to the approval of the department chairperson and the Dean or Director of ERI. Accurate and valid criteria are essential to nondiscriminatory rankings of the candidates. Some examples of selection criteria are: amount, relevance and quality of formal education; amount, relevance and quality of previous teaching experience; amount, relevance and quality of research activities, publications or presentations; ability to communicate effectively with students and staff, and involvement in professional organizations. Further information regarding development of valid selection criteria may be obtained by contacting the Office of Equal Opportunity.

In screening applicants, the Search Committee should first eliminate all persons who do not meet the stated minimum qualifications (non-qualified). The confidential affirmative action inquiry cards shall be sent to all qualified candidates by the Office of Equal Opportunity. The Search Committee shall provide the office with a list of names and addresses of all candidates who meet the minimum qualifications. It is to the committee's benefit to submit these names and addresses on a rolling basis in order to determine whether the pool is representative as early as possible in the process.

After initial screening, the Search Committee should evaluate the materials submitted by each of the remaining candidates. Consideration of each candidate should be based on the selection criteria developed by the Committee. Evaluation techniques must be uniformly applied to all candidates.

## On-Campus Interviewing

Following the screening and a review of data provided by the Office of Equal Opportunity from the affirmative action inquiries, the Committee shall recommend candidates to be interviewed, and section C of the Faculty Recruitment Record shall be completed by the Search Committee and reviewed by the Dean or Director of ERI, the Director of OEO and the Office of the Vice President for Academic Affairs. Where there is evidence that qualified minorities, women or persons with disabilities should be available in the potential pool of candidates, the Committee may be required to continue the search for qualified candidates. The decision to extend the search shall be made by the Office of the Vice President for Academic Affairs after consultation with the Dean or Director of ERI and the Director of OEO.

The objective of the campus interview phase is to assess an individual's qualifications to perform the required duties of the position, as designated by the job description and selection criteria. The Search Committee should ensure that all candidates are treated in an equivalent manner, both in respect to the substance of the interview and the arrangements on and off campus.

Upon completion of the interviews, the candidates shall be discussed by the Search Committee and a candidate or candidates recommended, in order of preference. Where two or more candidates possess similar qualifications, consideration shall be given to the impact the selected candidate will have on the achievement of OU's affirmative action goals.

At the conclusion of the process, section D of the Faculty Recruitment Record shall be completed by the Search Committee and reviewed by the Dean or Director of ERI, the Director of the Office of Equal Opportunity, and the Office of the Vice President for Academic Affairs, the

latter after consultation with the OEO. The committee is expected to support Section D by attaching a narrative. An example narrative can be found in Appendix A. The offer of employment shall be made by the Dean or Director of ERI for regular full-time faculty positions and for visiting appointments.

## **VI. VISITING FACULTY REAPPOINTMENT OR TRANSFER TO TENURE TRACK**

1. Following a tenure track search, special considerations may lead the University to appoint a person in the applicant pool to visiting status, rather than tenure track status. Such a person may at a later time be transferred to tenure track status with the Vice President for Academic Affairs' approval, without further search. If the search was initially for a visiting faculty appointment, this exception generally does not apply.
2. If, following a visiting appointment search, a person in the applicant pool is appointed to visiting status, that person may be reappointed to visiting status without further search.
3. In unusual circumstances, such as an illness occurring to a tenure track faculty member one week before the term begins, a unit may ask for a waiver to appoint a visiting faculty member.

## **VII. RECORD RETENTION**

The Office of the Vice President for Academic Affairs shall keep a position folder for each position filled. That folder shall contain the Faculty Recruitment Record, copies of the position description, advertisement(s), selection criteria, all applicants' resumes and other materials used to evaluate each candidate. At the conclusion of the search process, the academic unit shall forward a memorandum to the Office of the Vice President for Academic Affairs indicating whether the records have been forwarded (in labeled boxes) to the Kresge Archives or remain in the unit. These records will be retained for three years after the date of hire of the successful candidate.

The Office of Equal Opportunity shall retain all records of information received from the confidential affirmative action inquiry cards in a position file folder for three years after the date of hire of the successful candidate.

## **VIII. PART-TIME FACULTY APPOINTMENTS**

The Board of Trustees' policy of nondiscrimination and affirmative action in hiring and employment decision also applies to the appointment of part-time faculty. Efforts will be made by the library and each department and school to recruit qualified minorities, women and persons with disabilities for part-time faculty appointments.

The University recognizes that each unit has different practices and needs relative to the hiring of part-time faculty. Development of a uniform policy may not be responsive to these differing needs. Nonetheless, some monitoring of recruitment and hiring practices must be done to assure compliance with Board of Trustees' policies.

## **IX. WAIVERS**

Occasionally, there may be an immediate need to fill a faculty position, and inadequate time to conduct an appropriate search and follow the recruitment and screening procedures outlined above.

The Department Chairperson, Dean or Director of ERI shall prepare a written request for waiver of the requirements of the Faculty Hiring Procedures. The request shall detail which steps in these procedures should be foregone.

It shall also include a description of the position, the resume and other relevant information about any candidate proposed to fill that position, and the reasons why the requirements of the Faculty Hiring Procedures cannot be met.

Both the Office of the Vice President for Academic Affairs and the Director of the Office of Equal Opportunity shall receive copies of the waiver request. The OEO shall provide a written recommendation regarding the waiver request to the Office of the Vice President for Academic Affairs.

The waiver request must be approved by the Office of the Vice President for Academic Affairs and the Dean or Director of ERI, where the department chairperson makes the request. Consideration will be given to the department, school or college's equal opportunity efforts and accomplishments.

## **APPENDIX A**

### ***SAMPLE POSITION DESCRIPTION***

Assistant Professor - History Department

Tenure track position available for Fall, 1990, Ph.D. required. Minimum two years teaching experience. Preference is given to applicants with background in contemporary American history. A record of scholarly research, publication or presentations is desirable. Position responsibilities include teaching three courses per semester. Successful candidate will be expected to publish to receive tenure and be involved in university and community service.

### ***SAMPLE ADVERTISEMENT***

Assistant Professor of History  
Oakland University, Rochester, Michigan

OU's History Department, in the College of Arts and Sciences, invites applications for the tenure track position of Assistant Professor.

OU is a public institution of 12,000 students, with baccalaureate, master's and doctoral programs. It is adjacent to the recently developed Oakland Technology Park and convenient to the many social, cultural and recreational activities in the metropolitan Detroit area.

Responsibilities of this position include teaching three courses per semester. Scholarly research and publication is required to receive tenure, as well as involvement in university and/or community services.

Minimum qualifications are a Ph.D. degree and two years university teaching experience. A record of scholarly research publications and/or presentations is desirable. Preference will be given to candidates with a background in modern American history.



Please send vitae to:

Ms. J. Smith, Chair, Search Committee  
History Department, O'Dowd Hall  
Oakland University  
Rochester, Michigan 48309-4401  
(313) 370-1234

In order to ensure full consideration, applications must be received by May 1, 1996.

OU is an affirmative action/equal opportunity employer and encourages applications from women and minorities.

**APPENDIX B**

**OAKLAND UNIVERSITY  
FACULTY RECRUITMENT RECORD**

**Section A: Departmental Data**

Position Title: \_\_\_\_\_

Position Number: \_\_\_\_\_

Department/School: \_\_\_\_\_

Effective Date of Appointment: \_\_\_\_\_ Tenure Status: \_\_\_\_\_

**COMPOSITION OF SEARCH COMMITTEE**

Total# \_\_\_\_\_ Black \_\_\_\_\_ Total Other Minority\* \_\_\_\_\_ Female \_\_\_\_\_ Handicapped \_\_\_\_\_

(\*Minority includes Hispanic, American Indian, Alaskan Native, Asian or Pacific Islander.)

<b>DEPARTMENT EEO DATA</b>					
<b>FULL TIME:</b>	<b>White M/F</b>	<b>Black M/F</b>	<b>Hispanic M/F</b>	<b>Asian M/F</b>	<b>American Indian M/F</b>
Professors					
Assoc Professors					
Asst Professors					
Instructors					

**PLEASE ATTACH A COPY OF POSTING OR ADVERTISEMENT.**

Dean or director's of ERI approval:

Name: \_\_\_\_\_

Date: \_\_\_\_\_

**APPENDIX C**

**Section B: Recruitment Plan**

Identify all publications in which this position was advertised, all educational institutions or other organizations contacted, as well as individuals contacted for names of potentially qualified individuals. If any publication or source used is focused toward minorities or women, please indicate. This plan can be expanded during the search.

Name of Contact	Minority	Female
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

**APPENDIX C**

**APPLICANT DATA INFORMATION**

Pursuant to OU's Faculty Hiring Procedures, each recruiting college, school or department shall provide the Office of Equal Opportunity with a list of the names and addresses of all minimally qualified candidates that apply for vacant faculty positions. These individuals will be sent the Confidential Applicant Data card. To facilitate this process and ensure timely responses, please provide this information on a regular basis as applications are received. The form below may be completed and sent to the Office of Equal Opportunity, 148 North Foundation Hall, or you may call the office at 370-3496 with the information.

Position Title: \_\_\_\_\_ Position # \_\_\_\_\_

Dept: \_\_\_\_\_ Chairperson, Search Committee: \_\_\_\_\_

Closing date for receipt of applications: \_\_\_\_\_

Applicant Name	Date Materials Received
1.	
Address:	
2.	
Address:	
3.	
Address:	
4.	
Address:	
5.	
Address:	
6.	
Address:	
7.	
Address:	
8.	
Address:	
9.	
Address:	
10.	
Address:	

Position # \_\_\_\_\_

**Section C: Candidate Data**

Total applicants who meet *minimum* qualifications: \_\_\_\_\_ #Black \_\_\_\_\_ #Hispanic \_\_\_\_\_

#Total Other Minority \_\_\_\_\_ #Female \_\_\_\_\_ #Handicapped \_\_\_\_\_

**PLEASE ATTACH A COPY OF YOUR SELECTION CRITERIA.**

Applicant pool information for all candidates that are proposed to be seriously considered or interviewed. List name, race, sex and handicap status, if known, and specific reasons why candidate is recommended for serious consideration or interview. (*Attach extra sheets if necessary.*)

Name	To Be Interviewed (Yes/No)	Race	Sex	Handicapped (Yes/No)
1.				
Reason:				
2.				
Reason:				
3.				
Reason:				
4.				
Reason:				
5.				
Reason:				

**APPROVALS:**

Chairperson, Search Committee: \_\_\_\_\_ Date: \_\_\_\_\_

Chairperson, Department: \_\_\_\_\_ Date: \_\_\_\_\_  
(Where appropriate)

Dean or Director of ERI: \_\_\_\_\_ Date: \_\_\_\_\_

Office of Equal Opportunity: \_\_\_\_\_ Date: \_\_\_\_\_

Office of the Vice President  
for Academic Affairs: \_\_\_\_\_ Date: \_\_\_\_\_

**Section D: Recommended Candidates**

Department/School: \_\_\_\_\_ Position # \_\_\_\_\_

Position Title: \_\_\_\_\_ Tenure Status: \_\_\_\_\_

Rank: \_\_\_\_\_ Salary: \_\_\_\_\_ Effective Date: \_\_\_\_\_

Names of recommended candidates, *in order of preference*:

1. \_\_\_\_\_

2. \_\_\_\_\_

3. \_\_\_\_\_

A recruiting narrative must be submitted with Section D. An example is found in Appendix A.

**APPROVALS:**

Chairperson, Search Committee: \_\_\_\_\_ Date: \_\_\_\_\_

Chairperson, Department: \_\_\_\_\_ Date: \_\_\_\_\_  
(Where appropriate)

Dean or Director of ERI: \_\_\_\_\_ Date: \_\_\_\_\_

Office of Equal Opportunity: \_\_\_\_\_ Date: \_\_\_\_\_

Office of the Vice President  
for Academic Affairs: \_\_\_\_\_ Date: \_\_\_\_\_

**Appendix A**

Selection Criteria for Choosing Top 4 Applicants from Minimally Qualified List of 72.

The Recruiting Committee (present: Professor Michael Jones, Professor James Smith, professor Lucy Young, Professor Janet Williams; absent Professor Verne Jules) met to evaluate the 72 applicants. In reviewing the resumes, references, and other documents supplied by the applicants; the following selection criteria were applied.

Ph.D. in appropriate field.

Evidence of experience in teaching target course at undergraduate and/or graduate level.

Demonstrated research record with publications and presentations.

Perceived "fit" with unit needs

Courses to be taught and teaching flexibility.

Potential for interdisciplinary research.

#### Selection Criteria for Selecting Among Top 4 Applicants.

The top 4 applicants were invited to campus. The final applicant pool consisted of 2 non-minority females, 1 African American female, and 1 non-minority male. One non-minority female declined the invitation to visit campus.

The applicants were evaluated in a number of ways. Each applicant: taught a case analysis in an evening course; presented a research colloquium (advertised and open to all unit faculty); interviewed with departmental faculty, the Director of the graduate program, the Director of OIR; and toured campus facilities and surrounding community.

The Monday immediately following the last applicant visit, Recruiting Committee members conducted a group discussion with the members of the visited class to solicit their evaluations of the 3 applicants.

An applicant evaluation form for each applicant was submitted to all faculty and staff interacting with the applicant. These completed forms were returned to the search committee chair via campus mail.

The Recruiting Committee met to rate the final 3 applicants. The results of that analysis is presented below with summary comments.

#### Applicants Who Were Invited to Campus.

Name	Strengths	Weaknesses
Mr. X	Good Research Record (2 pubs, 5 pres). Research Area is mainstream. Interacted well with Faculty. Excellent recommendations. Has teaching experience. Has completed Ph.D. Industry experience.	Some question of research "fit" with other faculty for interdisciplinary work. Students rated him lowest of 3 applicants in teaching ability. No record of teaching perf. Some questions as to his motivation to fulfill service commitments since he asked how much time did he have to spend on campus. Industry experience is not directly related to field.
Ms. Y	Good rapport with students. Very personable. Good faculty interviews. Good recommendations.	Research record of concern. Has 3 presentations and no publications. Research subject is not mainstream. Has not collected data for dissertation. Interests may not permit interdisciplinary work. No record of teaching performance.
Ms. Z		Declined invitation to visit campus.

Ms. X	Best research record (6 pubs, 6 pres, 1 under review) Mainstream research topic. Good oral research presentation. Potentially good cross-disciplinary research. Rated highest teaching performance by students. Received a teaching award at current university. Good recommendations.	Has not yet analyzed dissertation data.
-------	--	---

Summary:

Ms. X was selected by the Committee as having both significantly better research and teaching performance than the other 2 applicants. She has more publications and presentations and has already begun a research stream with 1 additional article currently under review. She was considered by students to be the best teacher among the three because they felt she was better organized, seemed to have better command of the material, used prepared overheads, managed the class time well, and presented a good summary at the end of class. The Committee weighed heavily the Teaching Award as being objective evidence that she was a promising teacher.

**COMMITTEE**

**SEARCH ASSESSMENT CHECKLIST**

<b>Task I Develop the Search Strategy</b>	<b>Yes</b>	<b>N/A</b>	<b>NO</b>	<b>COMMENTS/NOTES</b>
Have you met with the Office of Equal Opportunity to discuss Oakland University faculty hiring procedures?				
Have you determined application and nomination deadlines and interview schedule?				
Have you listed potential data sources and target organizations and institutions?				

Have you specified sufficient sources for identifying minority and female candidates?				
Have you identified internal sources for potential candidates or referrals?				
Have you sought out electronic data bases?				
Have you determined what information you will require from candidates?				
<b>Task II Develop the Position Description and Selection Criteria?</b>				
Does the description include the University Equal Opportunity Statement?				
Are the selection criteria related to the essential qualifications and duties of the position?				
Have you prioritized the selection criteria?				
Is the position description written to attract the widest range of candidates?				



Is the position description diversity sensitive, unbiased and inclusive?				
Are the essential qualifications demonstrable, objective and/or measurable?				
Can the candidate be found in the real world?				
<b>Task III Post and Advertise</b>				
Has the position been posted in a range of journals, publications and other media?				
Has the committee identified key conferences and other events where the information can be shared?				
Have sources to enhance diversity been included?				
Has the committee appointed someone to coordinate this function?				
<b>IV Source and Recruit</b>				
Have you contacted minority and female caucuses within professional organizations and associations?				

Have you contacted minority and female scholars and administrators both external and internal?				
Have you involved alumni and community leaders as sources?				
Have you sent representatives to pertinent minority and female oriented conferences occurring during period of the search?				
Have you included phone and personal contacts as a key vehicle for sourcing and recruiting?				
Have you made direct contact with sources for enhancing diversity?				
Has committee proactively called other universities concerning this position?				
Has committee distributed advertisement to the rest of the department and asked for nominations?				

<b>Task V Screen and Evaluate the Pool</b>				
Have you developed a screening instrument to review applicants?				
Have you generated a sufficient pool of minority and female candidates to assure diversity in the final pool?				
Have you documented who was screened out and why?				
Has committee submitted names and addresses of minimally qualified individuals to the Office of Equal Opportunity in a timely fashion?				
<b>Task VI Conduct Interviews and Select Finalists</b>				
Have you prepared standard interview questions to be used with all candidates?				
Have you prepared a rating sheet?				
Do the interview questions pertain to the requirements of the position?				

Have you reviewed interview questions for bias?				
Have you verified education and prior employment?				
Have you assigned responsibility for reference checking?				

## Graduate Research Assistant Tuition Program

Attachment 5f

**Note:** Application must be submitted by the Faculty Advisor/Mentor or Unit Head.

- This Graduate Research Assistant Tuition (GReAT) Program is to supplement tuition support to **full-time ( $\geq 8$  credit hours/semester per OU policy)** graduate research assistant (GRA).
- The faculty advisor/mentor or unit head must provide evidence that the GRA is, or will be, receiving stipend support to conduct research during the period of GReAT support.
- Teaching Assistants (TAs) and recipients of any other scholarships are **not** qualified for GReAT.
- The GReAT Program allows for up to a total of 32 credit hours per student.  
(Up to 16 credit hours per academic year for a maximum of two years)

### Application Information

Student Last Name:	First Name:
Student # : G	Email: @oakland.edu
Major/Department:	Current GPA ( <b>must be <math>\geq 3.0</math> to be eligible</b> ):
Degree Sought: <input type="checkbox"/> Masters <input type="checkbox"/> Doctoral	Expected Date (mm/yy) of Graduation:
Mailing Address:	Phone#:

Apply For	Year	Stipend \$ Amount / Fund #	Credit Hours	Tuition \$ Requested	Submission Deadline	Graduate Study Review & Approval	GCSR Recommendation
Fall				\$	2 <sup>nd</sup> Monday of March (or May*)	2 <sup>nd</sup> Monday of April (or June*)	1 <sup>st</sup> Monday of May (or July*)
Winter				\$	2 <sup>nd</sup> Monday of October	2 <sup>nd</sup> Monday of November	1 <sup>st</sup> Monday of December
<b>TOTAL</b>				\$			

\* Applications submitted in response to the later deadline, usually for newly admitted students, are subject to budget availability.

### Faculty Endorsement

Faculty/Chair/Unit Head:	Email: @oakland.edu
Department:	Extension: Bld/Room:
School/College/	Title:

1. How long have you known the student applicant? In what capacity?
2. Please briefly describe the quality and qualification of the student applicant.

<b>Save</b>	<b>Print</b>
-------------	--------------

**SUBMIT** by *faculty*  
to Sponsored Research Office

**By submitting this application, I certify that information provided in this application is true.**

### Review & Recommendation (GCSR Office Use Only)

GCSR:	<input type="checkbox"/> Approve <input type="checkbox"/> Disapprove	Date:	Type in Name:
VP for Research:	<input type="checkbox"/> Approve <input type="checkbox"/> Disapprove	Date:	Type in Name:

## Chapter 6: Other Aspects of Sponsored Projects Administration

### 6.1 Preparation, Review and Submission of Sponsored Project Proposals

#### a. Proposal Preparation and Institutional Approval

Thoroughly read the program announcement and agency guidelines. The program announcement contains valuable information about format and timing of submissions. When reading the guidelines, pay careful attention to additional requirements for cost sharing, special approvals, letters of support/commitment, and special restrictions on the program.

Prior to submission of your proposal, you will need to obtain the review and approval of your departmental Chair and college Dean. Completion of the Electronic Grant Application (EGA) is required as the routing mechanism for proposal approvals. You will need to attach all documents required and route them with the GCSR electronic research management system electronically to the Grants Officer assigned for your sponsor. The Vice Provost for Research has institutional authorization to submit proposals on behalf of OU.

Web Link: [Electronic Grant Application](#)

Web Link: [Budget Checklist](#)

#### b. Generally, every proposal should include the following:

- 1) Title page. Unless a specific format is supplied by a sponsor, the following information should be included:
  - The name of the entity to which the proposal is being submitted
  - The name of Oakland University
  - The title of the proposed project
  - The name of the principal investigator and any co-investigators, with the school and departmental affiliation of each with OU
  - A place for the principal investigator's signature, a place for the signature of the Vice Provost for Research
  - The date of submission and the proposed project period

Certain standard information about OU, e.g., legal address, taxpayer identification number, DUNS number, can be found on the GCSR web site [www.oakland.edu/research](http://www.oakland.edu/research) under General Information.

**Error! Hyperlink reference not valid.**

- 2) Technical abstract. Depending on the scope and complexity of a project, an abstract may be of assistance to a prospective sponsor. The technical abstract should be a condensed version of the project, usually no more than 250 words. State concisely the significance of the project, what is expected to be accomplished and how, and the period of performance of the project.
- 3) Table of Contents. Including a table of contents, list of tables and figures may assist the proposal reviewer.

- 4) Introduction. The introduction (statement of need) emphasizes the importance of the project. The relationship of the project to the interests of the funding agency may be stressed here and should emphasize related research.
- 5) Objectives. The problem should be stated as specifically as possible. The importance and rationale of the proposed research should be well specified. It is important that the objectives, both general and specific, are well conceived based on related research. If the objectives are ill-defined, it may be due to an inadequate timeline or budget.
- 6) Methods and Procedures. This section details how the research will be carried out. The procedures may be written in several different ways, i.e., by activities tied to specific procedures, by functional categories such as planning, development, and implementation, or by major time blocks or activity phases.

If the sponsor limits the number of narrative pages, consider the use of tables or graphs in the appendix to conserve space. Some sponsors have limitations on use of appendices and what they may contain. Additional justification for unusually expensive or specialized equipment can be cross-referenced in this section to reinforce the budget request.

- 7) Dissemination of Findings. While research projects generally result in published papers in professional journals, many agencies require additional means of disseminating results. A statement of how this is to be done should be included.
- 8) Evaluation Plan (if required by sponsor). Some projects may require inclusion of a plan for evaluation of the success or progress of the project.
- 9) Equipment and Facilities. Most proposals should include a section on equipment and facilities available to the research project. Major items of equipment which are being requested are need to be clearly identified and their need described.
- 10) Budget and Budget Justification. For modular budgets, a budget justification is required that includes effort commitment of key personnel, anticipated supply items restricted under A-21, equipment, and subawards. A-21 restricted items that do not accompany the original budget with adequate justification will not be approved after the award.

Web Link: [Preparing Your Budget](#)

- 11) Biographical Data or Curriculum Vitae. Biographical information should be submitted with every proposal to indicate the background, areas of interest, research capabilities, and publications of the principal investigator and other professional investigators. Federal sponsors require a specific format for preparation of biographical data.

Web link: [PHS398 biosketch sample](#)

- 12) References. Proposals should include a list of references to pertinent literature in the field. The list should be as current as possible at the time the proposal is prepared, and should cite the most recent advances in the field.

- 13) Appendices or Supplementary Documentation. Appendices may be used to indicate data of peripheral benefit to the research, e.g., reprints of articles, subaward data, letters of support, tabular data, and graphs. Sponsors often limit the length and type of information that may be included within the appendix.

As of April 7, 2008, NIH funded peer-reviewed articles accepted for publication must be made available on PubMed Central within 1 year of publication. For NIH submissions of renewals or new applications after May 25, 2008, you will need to provide the PubMed Central ID number for publications funded by NIH.

- 14) Certifications. Federal agencies require a number of representations and certifications which must accompany each proposal. Some agencies such as NIH and NSF have incorporated these in their forms while others such as DOD, NASA, DOE and EPA have separate certification forms which must be completed by the Office of Grants, Contracts, and Sponsored Research. As part of the proposal process, the principal investigator, *must certify that the information submitted within the application is true, complete and accurate to the best of his/her knowledge; that any false, fictitious, or fraudulent statements or claims may subject him/her to criminal, civil, or administrative penalties; and agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application.*

### c. **Preparing Your Budget**

The principal investigator must estimate the costs of performing the research and provide adequate justification of those costs. Grant Officers are available to assist the principal investigator and business administrators in preparing a realistic budget.

- 1) Personnel, Wages, and Benefits. To determine total salaries and wages, list the percentage of effort to be spent by each person who will work directly on the project. Effort should be shown in terms of percentage of full-time effort or in person-months. For individuals paid on an academic year basis, show a breakdown between academic year and summer effort.

Some cautionary notes on personnel budgeting:

- Clerical or administrative personnel are generally unallowable as direct charges to a federally sponsored project.
- Sponsor funded activities will not result in any OU employee receiving compensation at a rate in excess of authorized salary.
- You must use the fringe benefit rate for the applicable employee class as authorized under Oakland's federally negotiated rate agreement OU Rate Agreement.
- Graduate research assistants receive tuition and may be eligible for tuition incentives funded by the Vice Provost for Research. Tuition assistance is considered *cost sharing* and will be counted towards fulfillment of a sponsor-mandated match commitment. If a match is not required by the sponsor, tuition should be proposed as sponsor funded. Tuition assistance is provided based on funds availability. You will be notified by the Grant Officer to apply for available tuition assistance if the proposal is awarded.

- 2) Materials & Supplies. A research project will usually consume expendable supplies and minor equipment such as laboratory items, instructional materials, animals, laboratory



notebooks, etc. A reasonable amount should be budgeted for these items. Office supplies are normally unallowable under federal awards unless specifically requested and justified as a programmatic need, i.e., a survey would require paper and envelopes. The purchase of computers for research purposes must also be justified in the proposal as directly related to the project and used exclusively for research purposes. Purchase of computers subsequent to the proposal without original justification will not be allowed as a direct charge. Refer to the OU Guidelines on A-21 restricted expenditures for additional guidance.

- 3) Travel. Reimbursement for travel expenses is subject to sponsor requirements and OU Administrative Policy and Procedure #1210. Many sponsors request specific data on each proposed trip, including destination, transportation costs, number of days of travel, and purpose of each trip. Domestic travel within the U.S. and Canada should be separately budgeted from foreign travel. **All foreign travel on federally funded projects must utilize US flag air-carriers whenever possible regardless of cost or convenience.** Refer to the OU Guidelines on Travel Regulations for additional information on this topic.
- 4) Equipment (excluded from indirect costs for MTDC). Capitalized equipment is university-owned equipment with a cost of \$5,000 or greater and a useful life of two years or more. All equipment purchases must be reported to the Property Office upon acquisition or prior to disposal (248) 370-4220. Proposals outlining equipment purchases must be supported with a justification of the need and how the amount was derived. Equipment purchases proposed in excess of \$10,000 require a vendor quote to substantiate the amount proposed. Purchasing & Risk Management requires a competitive bidding process for purchases above this limit.
- 5) Consultants. By definition, consultants are not employees of the University. Consultants should be budgeted only for tasks where on-campus expertise does not exist or is not readily available. Normally, consultants are paid a fee plus travel and other expenses. If travel is included in the fee, you will need to indicate this. In all cases, consultants should be contracted at a reasonable rate. In rare circumstances consultants are employees, when this occurs; consultants must be across academic disciplines and should be incorporated as personnel with applicable fringe benefits in the budget. A Personal Services Agreement should be completed for consultant costs. Refer to OU Policy #262 for guidelines on consultants.
- 6) Participant Support Costs (excluded from indirect costs for MTDC). Support for participants to attend conference/workshop program is provided for some sponsored programs. Participant support is defined in the funding announcement and does not include the personnel or travel costs associated with University personnel.
- 7) Subawards (Greater than \$25,000 is excluded from indirect costs for MTDC). Subawards are issued to complete a substantive portion of research or other programmatic activity. Sub-awardees must provide the statement or scope of work, budget, period of performance, negotiated F&A agreement to verify the indirect costs proposed, and the signature of a representative authorized to contractually commit the institution that can be in the form of a letter of intent. A subaward should be justified in the proposal as a necessary substantive portion of the research or other programmatic activity.

- 8) Other Direct Costs. Animal housing per diem, publication charges, reprints and page charges, postage (allowable as a direct charge ONLY when the scope of work includes recruitment of participants or surveys), equipment maintenance, long distance phone charges, campus services, etc. These charges should be anticipated and described as part of the budget narrative.
- 9) Facilities and Administrative Costs (F&A). Facilities and Administrative (F&A) costs, also called overhead or indirect costs, reimburse the OU for laboratory and office space, utilities, administrative services, library services, building, grounds, street and parking lot maintenance. In other words, it includes those things essential to support sponsored activities which are difficult to identify as a direct charged to a specific research grant or contract.

F&A cost percentages are determined periodically from actual cost records through a detailed cost accounting procedure and are audited and approved by the federal government. Full F&A costs should be charged on all projects, the only exceptions being for those sponsors that have a published policy that limits indirect cost recovery. Any exceptions to full F&A cost recovery must be approved by the Vice Provost for Research.

- 10) Cost Sharing. Some sponsors require a contribution to the total cost of the project as mandatory cost sharing. In addition to mandatory cost sharing, any contribution to a project included in the proposal, either in the budget as university funded effort or within the proposal narrative will be considered voluntary committed cost-sharing which OU must document. After-the-fact cost share (voluntary uncommitted) to a project that is not proposed is not required to be documented. At the proposal stage, the fund to which mandatory or voluntary committed cost sharing will be charged must be identified and approved by the Department Chair and the Vice Provost for Research.  
Cost shared direct costs should also include the associated F&A costs when determining the total amount of cost sharing committed in the proposal. Federal sponsors must pre-approve waived F&A as cost sharing. OU discourages cost sharing unless mandated by the sponsor.

## **6.2 Research Collaboration and Partnership**

### **a. Oakland University Model Agreement for Small Business Technology Transfer (STTR) Program**

This Agreement between COMPANY, a small business concern organized as a corporation under the laws of STATE and having a principal place of business at COMPANY ADDRESS, ("SBC") and OU, a Michigan institution of higher education and constitutional body corporate located in Rochester, Michigan ("OU"), is entered into for the purpose of allocating between the parties certain rights relating to an STTR project to be carried out by SBC and OU (hereinafter referred to as the "PARTIES") under an STTR funding agreement that may be awarded by the US AGENCY ("AGENCY") to SBC to fund a proposal entitled "*PROPOSAL TITLE*" (*topic number XXX-XXXX*) to be submitted, to AGENCY by SBC on or about DATE.

1) Applicability of this Agreement

- (a) This Agreement shall be applicable only to matters relating to the STTR project referred to in the preamble above.
- (b) If a funding agreement for an STTR project is awarded to SBC based upon the STTR proposal referred to in the preamble above, SBC will promptly provide a copy of such funding agreement to OU, and SBC will make a sub-award to OU in accordance with the funding agreement, the proposal, and this Agreement. If the terms of such funding agreement appear to be inconsistent with the provisions of this Agreement, the parties will attempt in good faith to resolve any such inconsistencies. However, if such resolution is not achieved within a reasonable period, SBC shall not be obligated to award nor OU to accept the subaward, as the case may be. If a subaward is made by SBC and accepted by OU, this Agreement shall not be applicable to contradict the terms of such subaward or of the funding agreement awarded by AGENCY to SBC except on the grounds of fraud, misrepresentation, or mistake, but shall be considered to resolve ambiguities in the terms of the subaward.
- (c) The provisions of this Agreement shall apply to any and all consultants, subcontractors, independent contractors, or other individuals employed by SBC or OU for the purposes of this STTR project.

2) Background Intellectual Property

It is possible that one or both Parties may possess rights in background intellectual property, that is, intellectual property not otherwise subject to this Agreement, which would be useful or essential to the practice or commercialization of the results of this Agreement. For example, the OU might own a patent which would be infringed by the SBC when it attempted to commercialize the results of this Agreement unless a license was obtained from the OU. Where the Parties determine that background technology may exist, consideration should be given to negotiating license rights which will allow the practice and commercialization of the results of this Agreement.

3) Project Intellectual Property

- (a) "Project Intellectual Property" means the legal rights relating to inventions (including Subject Inventions as defined in 37 CFR 401), patent applications, patents, copyrights, trademarks, mask works, trade secrets, and any other legally protectable information, including computer software, first made or generated during the performance of this STTR Agreement.
- (b) The rights of the Parties to subject inventions made by their employees in the performance of this STTR Agreement shall be as set forth in the Patent rights clause of 37 CFR 401.14. AGENCY may obtain title to any subject invention not elected by a party as set forth in the Patent rights clause.

Unless otherwise agreed in writing, Project Intellectual Property shall be owned by the party whose employees make or generate the Project Intellectual Property. Jointly made or generated Project Intellectual Property shall be jointly owned by the Parties unless otherwise agreed in writing. The SBC shall have the first option to perfect the

rights in jointly made or generated Project Intellectual Property unless otherwise agreed in writing.

In addition to the Government's rights under the Patent rights clause of 37 CFR 401.14, the Parties agree that the Government shall have an irrevocable, royalty free, nonexclusive license for any Governmental purpose in any Project Intellectual Property.

- (c) The Parties agree to disclose to each other, in writing, each and every Subject Invention, which may be patentable or otherwise protectable under the United States patent laws in Title 35, U.S.C. The Parties acknowledge that they will disclose Subject Inventions to each other within two (2) months after their respective inventor(s) first disclose the invention in writing to the person(s) responsible for patent matters of the disclosing Party. All written disclosures of such inventions shall contain sufficient detail of the invention, identification of any statutory bars, and shall be marked confidential, in accordance with 35 U.S.C. Section 205. Disclosures to AGENCY shall be within the time provided in paragraph (c)(1) of the Patent rights clause of 37 CFR 401.14.

#### 4) Follow-on Research or Development

All follow-on work, including any licenses, contracts, subcontracts, sublicenses or arrangements of any type, shall contain appropriate provisions to implement the Project Intellectual Property rights provisions of this Agreement and insure that the Parties and the Government obtain and retain such rights granted herein in all future resulting research, development, or commercialization work.

#### 5) Confidentiality/Publication

- (a) Background Intellectual Property and Project Intellectual Property of a party, as well as other proprietary or confidential information of a party, disclosed by that party to the other in connection with this STTR project shall be received and held in confidence by the receiving party and, except with the consent of the disclosing party or as permitted under this Agreement, neither used by the receiving party nor disclosed by the receiving party to others, provided that the receiving party has notice that such information is regarded by the disclosing party as proprietary or confidential. However, these confidentiality obligations shall not apply to use or disclosure by the receiving party after such information is or becomes known to the public without breach of this provision or is or becomes known to the receiving party from a source reasonably believed to be independent of the disclosing party or is developed by or for the receiving party independently of its disclosure by the disclosing party.
- (b) Subject to the terms of paragraph (a) above, either party may publish its results from this STTR project. However, the publishing party shall provide the other party a thirty (30) day period in which to review proposed publications, identify proprietary or confidential information, and submit comments. The publishing party shall not publish or otherwise disclose proprietary or confidential information identified by the other party and the publishing party will give full consideration to all comments before publication. Furthermore, upon request of the reviewing party, publication will be deferred for up to sixty (60) additional days for preparation and filing of a patent application which the reviewing party has the right to file or to have filed at its request by the publishing party.

6) Liability

- (a) Each party disclaims all warranties running to the other or through the other to third parties, whether express or implied, including without limitation warranties of merchantability, fitness for a particular purpose, and freedom from infringement, as to any information, result, design, prototype, product or process deriving directly or indirectly and in whole or part from such party in connection with this STTR project.
- (b) SBC will indemnify and hold harmless OU with regard to any claims arising in connection with commercialization of the results of this STTR project by or under the authority of SBC.

7) Termination

- (a) This Agreement may be terminated by either Party upon sixty (60) days written notice to the other Party. This Agreement may also be terminated by either Party in the event of the failure of the other Party to comply with the terms of this Agreement.
- (b) In the event of termination by either Party, each Party shall be responsible for its share of the costs incurred through the effective date of termination, as well as its share of the costs incurred after the effective date of termination, and which are related to the termination. The confidentiality, use, and/or non-disclosure obligations of this Agreement shall survive any termination of this Agreement.

AGREED TO AND ACCEPTED:

Small Business Concern

By: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

Oakland University

By: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

**b. OU Mutual Non-Disclosure Agreement**

The non-disclosure agreement (NDA) is a contract between Oakland University and the external party. The NDA must be executed under the organizational signatory authority policy by a person authorized to sign on behalf of Oakland. Changes to the standard agreement must be reviewed and approved by Legal Affairs prior to execution. [\(Attachment 6a\)](#)

The Exhibit I of the NDA is an agreement between Oakland University and its employee. Exhibit I should be read and signed, if the employee agrees to the NDA conditions, after Oakland's execution of the NDA. It is binding between Oakland and the signing party for the entire period of agreement irrespective of a subsequent severance of the employment relationship. [\(Attachment 6b\)](#)

## OU Mutual Non-Disclosure Agreement

## Attachment 6a

This Mutual Non-Disclosure Agreement (Agreement) is made by and between Oakland University, a Michigan institution of higher education and constitutional body corporate located in Rochester, Michigan (University) and \_\_\_\_\_, a \_\_\_\_\_ organized and existing under the laws of the State of \_\_\_\_\_, with its registered office located at \_\_\_\_\_ (Company).

### Recitals

WHEREAS, the parties to this Agreement contemplate that they may enter into one or more contracts and/or collaborative relationships involving the exchange of scientific, technical, or other information which is considered by the party owning such information to be proprietary, confidential, and of value to that party; and

WHEREAS, each party is willing to disclose such information to the other party for the purposes of discussing collaborative efforts to promote the increase of useful knowledge, and/or carrying out the scope of work in any contract to be negotiated and executed by and between them; and

WHEREAS, the parties desire to preserve and protect the confidentiality of the information disclosed and their respective rights in such information to the extent reasonable and practicable under the contracts and agreements formed between them;

NOW, THEREFORE, in consideration of the foregoing Recitals and the mutual promises and conditions contained in this Agreement, the parties, and each of them, do hereby further covenant and agree as follows:

### Agreement

#### 1.0 Term.

The term of this Agreement will be \_\_\_\_\_ year(s) commencing on \_\_\_\_\_ (Commencement Date) and ending on \_\_\_\_\_ unless sooner terminated as provided herein or extended by written agreement of the parties.

#### 2.0 Confidential Information.

2.1. "Confidential Information" as used in this Agreement means all information related to a party's business, technical, and research activities including without limitation trade secrets or commercial or financial information, data, processes, products, solutions, technical and business documents, know-how, software, invention disclosures, licenses, potential or actual licensing partners, and other subject matter capable of protection under the laws governing patents, copyrights and other intellectual property, and disclosed to the other party starting on the Commencement Date. No information will be regarded as Confidential Information if the receiving party can show by competent evidence that such information:

- a. was, at the time of disclosure, already known by the receiving party, as shown by written records in the possession of the receiving party; or
  - b. was at or subsequent to the time of disclosure, through no fault of the receiving party, known to the general public through publication or otherwise; or
  - c. was, subsequent to disclosure to the receiving party, lawfully and independently received by the receiving party from a third party who or which had the right to disclose such information without restriction.
- 2.2 Specific aspects or details of Confidential Information will not be deemed to be within the public domain or in the possession of the receiving party merely because the Confidential Information is embraced by general disclosures in the public domain or in the possession of the receiving party. In addition, any combination of Confidential Information will not be considered in the public domain or in the possession of the receiving party merely because individual elements thereof are in the public domain or in the possession of the receiving party unless the combination and its principles are in the public domain or in the possession of the receiving party.
- 2.3 The parties understand that certain of either party's Confidential Information may be subject to existing confidentiality or other nondisclosure agreements between each party and various third parties ("Third Party Confidential Information"). In cases concerning Third Party Confidential Information, each party will obtain permission from the third party discloser to share Third Party Confidential Information with the other party, and the receiving party will observe any restrictions to which the Third Party Confidential Information may be subject, including without limitation restrictions mandated by the Confidential Research and Investment Information Act, the Bayh-Dole Act, or any other such regulation.
- 2.4 Neither party is under any obligation to provide to the other party with any Confidential Information; rather, the parties may at their sole and absolute discretion determine which of their Confidential Information will be provided to the other party.
- 2.5 The receiving party obtains no rights nor any express or implied license nor any right to obtain any express or implied license under any of the disclosing party's patents, patent applications, or know-how, by this Agreement or by any disclosure of any Confidential Information.
- 2.6 Any obligation of confidentiality may be waived in writing by either party as to particular Confidential Information and to a particular use or disclosure. Any such waiver shall have a one-time effect and shall not apply to any subsequent situation regardless of its similarity.
- 3.0 Obligations of the Party Receiving Confidential Information.
- 3.1 All Confidential Information will remain the property of the disclosing party and, upon the disclosing party's request, the receiving party will promptly return to the

disclosing party all Confidential Information, or any part, compilation, or reproduction thereof, in the receiving party's possession.

- 3.2 With respect to Confidential Information, the receiving party will:
- a. treat the Confidential Information as confidential and preserve and protect the Confidential Information's confidentiality;
  - b. use the Confidential Information solely in connection with this Agreement and under any and all contracts, grants and agreements formed between or among the parties of which this Agreement will be made a part;
  - c. make no disclosures of any portion of the Confidential Information to any third party;
  - d. limit access to the Confidential Information to those designated recipients having a need to access the Confidential Information; and who have executed an acknowledgement in the form of Exhibit 1 attached hereto;
  - e. maintain in confidence any Confidential Information regarding the nature or scope of any transaction and proposed transactions between the parties, except to the extent such Confidential Information must be disclosed pursuant to law, and then only after notifying the other party of such requirement and affording the other party sufficient opportunity to oppose the legal obligation to disclose the Confidential Information; and
  - f. not use any of the Confidential Information for any purpose other than for the purposes of discussing collaborative efforts to promote the increase of useful knowledge, and/or carrying out the scope of work in any contract to be negotiated and executed by and between them. Specifically but without limitation, neither party will (i) use any of the other party's Confidential Information for any commercial purpose or development of any products or technology; (ii) use or attempt to use the other party's Confidential Information without first entering into an agreement with the other party; or (iii) refer to or incorporate any part of the other party's Confidential Information in the other party's own Confidential Information or patent prosecution.
- 3.3 The Company acknowledges that the University complies with the State of Michigan Freedom of Information Act (FOIA) and Confidential Research and Investment Information Act (CRIIA), both as may be amended from time to time. Accordingly, the parties agree that for all Confidential Information to which the FOIA or CRIIA applies, the University will, to the extent allowed by law, hold all such Confidential Information in trust and not to disclose any of such Confidential Information, by publication or otherwise, to any person other than those persons whose services require access to such Confidential Information on a need-to-know basis for the purposes of carrying out the terms of this Agreement.



3.4 Each party will comply with all applicable laws, rules and regulations, including Export Administration Regulations and Export Control Regulations of the United States of America, relating to the export or re-export of Confidential Information, insofar as they relate to the Confidential Information disclosed under this Agreement.

#### 4.0 Publications.

4.1 The University, as a Michigan institution of higher education, engages only in research that is compatible, consistent, and beneficial to its academic role and mission. Therefore, significant results of research activities must be reasonably available for publication. The Company acknowledges that the University will have the right to publish data, information and results relating to the same subject matter as the Confidential Information. The University will, however, during the term of this Agreement, coordinate with the Company before disseminating such data, information or results, including without limitation participation in symposiums or submitting publications by giving the Company a thirty (30) calendar day period in which to review proposed publications and submit comments, which will be given full consideration before publication. In addition, upon the written request of the Company, publication will be deferred for up to ninety (90) additional calendar days for preparation and filing of a patent application which the Company has the right to file. This term may be extended by mutual written agreement of the parties, which agreement shall be reasonably given.

4.2 The Company will not include the name of the University in any advertising, sales promotion, or other publicity matter without the prior written approval of the University.

#### 5.0 Default.

A party will be in default of its obligations under this Agreement if such party fails to observe, to comply with, or to perform any term, condition, or covenant contained in this Agreement and such failure continues for ten (10) calendar days after the non-defaulting party gives the defaulting party written notice thereof. If the default is not timely cured, the non-defaulting party may terminate this Agreement immediately and/or seek such other and further relief as may be provided by law, including equitable relief including without limitation an injunction or restraining order as required to prevent unauthorized disclosures of Confidential Information.

#### 6.0 Termination.

6.1 Either party may terminate this Agreement by giving the other party thirty (30) calendar days' prior written notice in accordance with the Notice provisions of this Agreement.

6.2 This Agreement will terminate immediately upon default as provided in paragraph 5 or by a default by any obligation, term, condition or covenant contained in any contracts or agreements formed between them of which this Agreement is made a part.

6.3 The obligations of confidentiality contained in this Agreement will survive termination of this Agreement for a period of five (5) years for any Confidential Information disclosed during the term of this Agreement.

6.4 Within sixty (60) calendar days following termination of this Agreement, the receiving party will return or destroy any of the disclosing party's Confidential Information which may remain in the receiving party's possession, and will provide written certification to the disclosing party that all of the disclosing party's Confidential Information has been returned or destroyed. The disclosing party will choose the appropriate option, delivery or destruction, for the receiving party to follow.

7.0 Notices.

All notices and other correspondence related to this Agreement must be in writing and will be delivered by certified mail, return receipt, or by facsimile transmission if a fax number is shown below and notice of receipt is provided, addressed as follows:

If to University:  
T.C. Yih  
Vice Provost for Research  
Office of Sponsored Research  
544 O'Dowd Hall  
Rochester, Michigan 48309  
Tel: (248) 370-2552  
Fax: (248) ( 370-2973  
E-mail: yih@oakland.edu

If to Company:  
(Name) \_\_\_\_\_  
(Dept) \_\_\_\_\_  
(Street) \_\_\_\_\_  
(City, State, Zip) \_\_\_\_\_  
Tel: \_\_\_\_\_  
Fax: \_\_\_\_\_  
E-mail: \_\_\_\_\_

8.0 Legal Authority.

Company warrants that it possesses the legal authority to enter into this Agreement and that it has taken all actions required by its procedures, bylaws, and/or applicable law to exercise that authority, and to lawfully authorize its undersigned signatory to execute this Agreement and to bind it to the terms of the Agreement. The person(s) executing this Agreement on behalf of Company warrant(s) that such person(s) have full authorization to execute this Agreement.

9.0 Entire Agreement.

This Agreement constitutes the entire agreement between the parties, and supersedes any previous contracts, understandings, or agreements of the parties, whether verbal or written, concerning the subject matter of this Agreement.

10.0 Waiver.

No delay or failure to enforce any provision of this Agreement will constitute a waiver or limitation of rights enforceable under this Agreement.

11.0 Amendment.

No amendment to this Agreement will be valid unless it is made in a writing signed by the authorized representatives of the parties.

12.0 Severability.

In the event that a court of competent jurisdiction finds any provision of this Agreement invalid and/or unenforceable, the remaining provisions shall remain valid and in force, and said court will reform the invalid and/or unenforceable clause(s) to render them valid and enforceable and, to the extent possible, to conform to the intent of the parties.

13.0 Governing Law.

This Agreement will be construed and enforced according to the laws of the State of Michigan and all procedural and substantive legal issues arising from or relating to this Agreement, including performance or non-performance hereunder, shall be resolved by resort only to the procedural and substantive laws of the State of Michigan without resort to any conflict of laws analysis.

14.0 Assignment.

This Agreement, and the rights and obligations of the parties hereunder, may not be assigned by either party without the express written consent of the other party. This Agreement shall be binding on and shall inure to the benefit of the parties and their successors and permitted assigns.

IN WITNESS WHEREOF, the undersigned, duly authorized representatives of the parties execute this Agreement.

OAKLAND UNIVERSITY

By: \_\_\_\_\_

T.C. Yih  
Vice Provost for Research

By: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

**EXHIBIT 1**  
**TO**  
**OAKLAND UNIVERSITY**  
**MUTUAL NON-DISCLOSURE AGREEMENT**

**Attachment 6b**

Pursuant to a Confidentiality Agreement made by and between Oakland University (University) and \_\_\_\_\_, Inc. (Company) dated \_\_\_\_\_ (Non-Disclosure Agreement), I acknowledge and agree to the following terms:

1. I have read the Non-Disclosure Agreement.
2. I agree to be bound by all provisions of the Non-Disclosure Agreement and any subsequent revisions or amendments thereto.
3. I agree that all personnel conducting project-related research under my direction or control will abide by the provisions of the Non-Disclosure Agreement and any subsequent revisions or amendments.
4. I recognize that during work subject to the Non-Disclosure Agreement and/or any and all contracts and agreements formed between the University and the Company of which this Non-Disclosure Agreement will be made a part, certain employees of the University and the Company may have access to confidential and proprietary information furnished by either the University or the Company. Such information may include, but is not limited to, trade secrets or commercial or financial information, data, processes, products, solutions, technical and business documents, know-how, software, invention disclosures, licenses, potential or actual licensing partners, and other subject matter capable of protection under the laws governing patents, copyrights and other intellectual property.
5. I understand that the University and the Company have agreed to hold in strict confidence the other's confidential and proprietary information and will not duplicate, use or disclose said information except as permitted under the Non-Disclosure Agreement or any contracts or agreements formed between the University and the Company of which the Non-Disclosure Agreement is a part.
6. I promise that I will maintain at all times the confidentiality of information as required by the Non-Disclosure Agreement and for the length of time provided in the Non-Disclosure Agreement.
7. I understand that breach of my promise may expose me and/or my employer to liability, and that I will be responsible to my employer if I violate the required confidentiality.
8. I understand that if either the University or the Company should file suit against me in my own name for violation of the confidentiality promises by the University or the Company, respectively, my employer may or may not choose to provide a defense or pay any damages for which I may become liable.

9. Should I choose to no longer participate in the work covered by the Non-Disclosure Agreement or any contract or agreement formed between the University and the Company of which this Non-Disclosure Agreement is a part, I understand that I must notify my employer of my decision in writing.
  
10. I understand that all of the University's and the Company's confidential and proprietary information remains the property of the University and the Company, respectively, and I do not have any right or license under any of the University's or the Company's patents, patent applications, or know-how, by the Non-Disclosure Agreement or by any contract or agreement formed between the University and the Company of which this Non-Disclosure Agreement is a part or by any disclosure of any of the University's or the Company's confidential or proprietary information to me.

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

## **Chapter 7: Environmental Health and Safety**

### **7.1 Charge to the Laboratory Safety Committee**

In April of 1994 an ad hoc chemical safety committee was formed at Oakland University (OU) to address chemical management in an academic and research environment. Membership of this committee was drawn from various departments responsible for laboratory chemical management and was given the name "Laboratory Safety Committee" or "LSC".

#### **a. Charge to the Committee**

The university's LSC is charged with the following:

- 1) Assist departments in implementing safe work practices in the laboratory
- 2) Ensure compliance with the OSHA Laboratory Standard
- 3) Review departmental chemical hygiene concerns
- 4) Evaluate injury and illness trends in the laboratory and recommend corrective measures to prevent injury and illnesses.
- 5) Periodic review of the LSC charge to ensure LSC effectiveness.

#### **b. Membership**

Faculty member appointments will be determined by the participating Department's Chair, Dean or Director. OU's LSC is represented by a minimum of one voting member from each of the following Units:

- 1) Biological Research Support Facility (BRSF)
- 2) Department of Biological Sciences
- 3) Department of Chemistry
- 4) Department of Physics
- 5) School of Health Sciences
- 6) School of Education and Human Services
- 7) School of Engineering
- 8) School of Nursing.

The following voting members will have a continuous appointment on the committee:

- 1) Laboratory Compliance Manager (Laboratory Safety Committee Chair)
- 2) Laboratory Compliance Specialist

3) Environmental Health and Life Safety Manager

The LSC will form ad hoc committees as necessary to address specific safety concerns.

**c. Reporting Requirements**

The Chair of the LSC will provide copies of the Laboratory Committee Minutes to the Vice Provost for Research and to the Associate Vice President for Finance and Administration.

**7.2 Environmental Health and Fire Safety**

OU's Environmental Health and Fire Safety Policy (Administrative Policy 620) is a subcomponent of the "Health and Safety," section found in OU's Administrative Policy and Procedures Manual. This Environmental Health and Fire Safety Policy provides information to OU on issues related to occupational and environmental health and safety, and fire and life safety. The Office of Environmental Health and Safety (EH&S) is responsible for the development, implementation and management of the University policies and procedures that are designed to protect employees from occupational illness/injury, protect campus persons and buildings from fire, protect OU from fines and penalties for failure to comply with environmental health and safety rules and regulations, and protect the environment and surrounding community from injury/illness resulting from improper handling/disposal of hazardous materials on campus. This policy applies to all faculty, staff, students, vendors, contractors and visitors on campus.

**a. Procedures Summary**

Environmental Health and Life Safety Policy 620 provides procedures for the following:

- 1) Ensuring Regulatory Compliance
- 2) Emergency procedures for fire emergencies, fire safety systems and building code.
- 3) Laboratory Safety including audit frequency, disciplinary action, and responsibilities for maintaining a safe laboratory environment.
- 4) Hazardous Waste Management

**b. Authority**

The Office of Environmental Health and Safety (EH&S) shall be notified immediately of any regulatory inspection agency, and has the authority to enter university premises for the purpose of inspection, investigations of injuries/illness or in response to complaints/violations. EH&S has the authority to cease any activity deemed to be dangerous to life and property.

Website Link: OU's Environmental Health and Fire Safety Policy (Administrative Policy 620) <http://www2.oakland.edu/audit/POLCY620.doc> (**Attachment 7a**)

### 7.3 Emergency and Hazardous Materials Response

Emergency and Hazardous Materials Response guidelines for university labs are covered in section X of the University's Hazardous Waste Management Guidelines, in section 2 of OU's Chemical Hygiene Plan and a comprehensive plan covering campus wide emergency response is detailed in the OU's Emergency Response Plan maintained by the OU Police. These guidelines cover chemical spills and accidents, personal contamination or injury and fire or fire related emergencies.

#### a. Response to Chemical Spills/Incidents

- 1) Assessing the Type of Spill: Incidental or Emergency
  - Incidental Release. Release of hazardous wastes whose characteristics are fully understood, present a negligible hazard and are easily controlled by "Trained" individuals.
  - Emergency Release - an accidental release of a hazardous waste which does not meet the criteria of an "Incidental Release," and consequently requires the response of personnel outside the immediate release area (this could include EH&S employees, OU Police and/or external emergency response personnel).
  
- 2) Responding to "Incidental" Spills
  - People in the immediate area of the spill should be alerted.
  - Spills should only be cleaned up by "trained" personnel.
  - If spill takes place in a lab:
    - Make sure room ventilation, fume hood or if equipped, room exhaust purge is active.
    - Trained lab responder must be certain to use appropriate personal protective equipment, at a minimum gloves, goggles, and lab coat.
  - Use spill kit appropriate for the material spilled
  - Dispose of contaminated materials appropriately. EH&S can be contacted for disposal instructions if uncertainty exists regarding how to handle the waste
  
- 3) Responding to "Emergency" Spills
  - Evacuate the room
  - Keep unauthorized personnel at least 25 feet from the room/area.
  - Door(s) to affected room(s) should be closed.
  - Call "911" on a University business phone or (248) 370-3331 to connect directly to OU Police Dispatch.
  - Be prepared to provide the OU Police dispatcher details of the emergency spill.
  - OU Police will dispatch the following to the spill area:
    - One or more OU Police officers
    - Office of Environmental Health for preliminary assessment and mitigation procedure/recommendations.
  - The Office of Environmental Health and Safety is available for guidance and advice for all chemical spills and accidents. If EH&S is not readily available, the Chair of the Department of Chemistry, Chemistry Laboratory Managers and Chemistry Faculty serving on the LSC can provide guidance.

Additional information regarding Emergency and Hazardous Materials Response may be found in the following Documents.



- OU's Chemical Hygiene Plan - Section 2.7  
See Research Policy – Section 7.4
- OU's Hazardous Waste Management Guidelines – Section X  
See Research Policy – Section 7.9
- OU's Emergency Response Plan –(Available through OU Police)
- OU Police Emergency Desktop Emergency Guide  
<http://www.oakland.edu/guide>

#### **7.4 Chemical Hygiene Plan**

The Occupational Safety and Health Administration's (OSHA) Laboratory Standard requires employers to convey chemical health and safety information to their laboratory employees and, ensure that proper work practices/procedures are in place to protect the worker. OU's Laboratory Chemical Hygiene Plan is a requirement of the OSHA Laboratory Standard and the university's guide to laboratory chemical safety. A copy of the Chemical Hygiene Plan is located in the laboratories and is also available upon request to all university laboratory workers. For assistance in laboratory chemical safety please call (248) 370-4314 or (248) 370-4603.

##### **a. OU Chemical Hygiene Plan**

Web Link: <http://www4.oakland.edu/?id=6070&sid=201>

##### **b. Chemical Hygiene Plan Forms**

- 1) Site-Specific Laboratory Safety Training Checklist ([Attachment 7b](#))
- 2) Laboratory Safety Audit Checklist ([Attachment 7c](#))

##### **c. Regulations**

- 1) Part 431 – Hazardous Work in Laboratories

Web Link: [http://www.michigan.gov/documents/CIS\\_WSH\\_part431\\_35623\\_7.pdf](http://www.michigan.gov/documents/CIS_WSH_part431_35623_7.pdf)

##### **d. Laboratory Chemical Inventory (LCI)**

The Laboratory Chemical Inventory is a critical component of chemical management at OU. We strongly encourage the monitoring of hazardous materials on a continuous basis and require a physical inventory at least annually or as requested by the Chemical Hygiene Officer.

The Laboratory Chemical Inventory is also required to maintain compliance with local, state, and federal regulations as well as provide critical information to responders during an emergency.

OU's LCI is maintained and updated by lab Principal Investigators, Supervisors or Department Laboratory Managers. EH&S regularly publishes updated copies of the LCI for use by OU Police and other local emergency responders.

The following link is used to update laboratory information to the LCI:

Web Link: [https://www2.oakland.edu/research/research\\_new/pages/staff\\_tools\\_login.cfm](https://www2.oakland.edu/research/research_new/pages/staff_tools_login.cfm)

#### e. **Laboratory Right-To-Know Training**

This course is required for all OU individuals that work in or around the laboratories where hazardous work may be performed, and/or where hazardous materials are handled or stored. Individuals are required to take this course before working in the laboratory. The course details OU's Chemical Hygiene Plan and includes instructions and training in safe standard laboratory work practices, use of personal protective equipment, health and safety information for chemical hazard classes, MSDS, and toxicology overview. Training also reviews emergency preparedness and response procedures.

In addition to the General Laboratory Right-To-Know training, **Site Specific training** is required and will be provided to individuals who will conduct or observe work with chemicals in the laboratory. It is to be conducted and documented by the Principal Investigator (PI), laboratory supervisor, or a designee. It is designed to address the specific hazards that may be associated with specific work and the laboratory environment.

This course fulfills the general requirements under the MIOSHA Part 431 Rules for Hazardous Work in Laboratories.

#### **7.5 Radiological Hazards**

Environmental Health and Safety (EH&S) is responsible for ensuring compliance with OU's broad scope radioactive materials license and to provide a safe work environment for all university employees permitted to use radioactivity. Please contact the university's Radiation Safety Officer (RSO) at (248) 370-4196 for assistance with radioactive materials or radiation generating machines.

Radioactive material (including machinery producing ionizing radiation) can only be used by authorized OU permit holders or under the supervision of a permit holder. User permits are issued by the OU Radiation Safety Committee (RSC). User permits are issued to the full-time OU faculty members or principal investigators only. All others must work under the supervision of a full-time faculty member.

Full-time faculty members can apply to the RSC for a user permit by submitting a Radiation User Permit Application. Please contact the RSO, to get the electronic copy. The committee will issue a user permit only after reviewing the application. Three-year user permits are issued after an initial probationary one-year user permit. Permit holders are responsible for the proper use of all radioisotopes or radiation producing machinery, proper maintenance of the facilities used for research, and proper maintenance of all required records. The specific, detailed instructions on procedures and requirements for the use of radioactive materials at OU are referenced in the OU Safety and Procedures Manual for the Use of Radioisotopes in Laboratories (see 7.5.a and 7.5.c).

Permit holders are responsible for meeting OU training requirements and standards. Every individual working with, or in the vicinity of radioactive materials, must receive instruction and training commensurate with their duties before beginning any work. In addition, all individuals must be retrained once every three years and/whenever there is a significant change in duties, regulations, or terms of the university's license of the investigators user permit. A description of these requirements can be found in the OU Safety and Procedures Manual for the Use of Radioisotopes in Laboratories (see 7.5a and 7.5c).

Permit holders should know that federal and state agencies routinely conduct inspections – some unannounced – including inspections of records maintained by permit holders. In addition, periodic audits of laboratories, and inspections of isotope records, are conducted by the RSO or a member of the RSO's staff. All inspections, including inspections of records, will be done as to minimize the disruption of normal laboratory functions. They will be unannounced.

For questions regarding radiation safety and/or radiation permits contact the RSO, at 248-370-4314, email [luongo@oakland.edu](mailto:luongo@oakland.edu) or visit the Laboratory Safety and Compliance web page.

**a. Radiation Safety and Procedure Manual**

The OU policy on the use of radiation on laboratories may be found at the link below.

[http://www2.oakland.edu/research/research\\_new/pages/files/File/Radiation\\_Manual.pdf](http://www2.oakland.edu/research/research_new/pages/files/File/Radiation_Manual.pdf)

**b. Radiation Safety Services**

- 1) Radioactive Waste Management Services: (Contact RSO @ extension – 4314)  
OU's Office of Environmental Health and Safety (EH&S) manages the disposal of radioactive and mixed waste for OU's Radiation Safety Program. All radioactive waste handling procedures are conducted in compliance with applicable Nuclear Regulatory Commission and Michigan Department of Environmental Quality Regulations. Radioactive wastes which have half-lives that allow for ten-half-life decay within three years will be temporarily stored for decay, surveyed and then disposed by drain or the regular trash. Radioactive mixed waste or radioactive liquid industrial waste is transferred to a licensed radioactive waste treatment storage disposal facility.
- 2) Radioactive Safety Training: (Contact RSO to arrange for training)  
Description: This course is provided for individuals who are authorized to work with radioactive materials and is mandatory prior to working with the material. The Radiation Safety training provides information about policies and procedures at OU that ensures compliance with State and Federal licensure. Radiation safety training includes topics such as a brief introduction to radiation physics, biological effects and the risks of radiation exposure, basic principles of radiation protection, exposure limits, personnel monitoring for radiation exposure, rights and responsibilities of radiation workers, good work practices, isotope storage and security, contamination control techniques, radiation measurements and calculations, the proper and safe handling of radioactive waste, and emergency response and accident recovery. Annual refresher training is required to stay informed of changes and review safe practices.

Requirements: OU's state and federal licensure for the use of radioactive material requires this training. All Permit holders and individuals at OU working with, or in the vicinity of, radioactive materials or radiation-generating machines must receive instructions and training commensurate with their duties before beginning any radiation work.

Training Programs Offered:

- Radiation Awareness Training: Any university employee who may enter radiation use areas, but not working directly with radiation.
- Basic Nuclide Training: Laboratory workers using radioactive materials.

- X-Ray Generating Machines Training: Laboratory workers operating machines that generate X-rays (EM, X-Ray Diffraction, X-Ray cabinets, etc.)

**c. Radiation Safety Forms**

- 1) Isotope Usage Log  
<http://www4.oakland.edu/upload/docs/labsafety/Isotopelog.pdf> (**Attachment 7d**)
- 2) Area Swipe Test Form (**Attachment 7e**)
- 3) Record of Prior Training and Experience Form (**Attachment 7f**)
- 4) Site Specific Training Form  
<http://www4.oakland.edu/upload/docs/labsafety/SiteSpecificTrain.doc> (**Attachment 7g**)
- 5) Radioactive Material Transfer Form  
<http://www4.oakland.edu/upload/docs/labsafety/RadTransfer.doc> (**Attachment 7h**)
- 6) Radioactive User Permit Form  
[http://www.oakland.edu/upload/docs/LabSafety/Application\\_to\\_use\\_Radiation\\_2008.doc](http://www.oakland.edu/upload/docs/LabSafety/Application_to_use_Radiation_2008.doc) (**Attachment 7i**)

**d. Regulations and Guidelines**

Federal and State agencies regulate the use of radioactive materials. For more information see the links below.

Nuclear Regulatory Commission (NRC)

- 1) 10- CFR Part 20 - Standards For Protection Against Radiation  
(<http://www.nrc.gov/reading-rm/doc-collections/cfr/part020/index.html> )  
(Attachment- Detailed Table of Contents)
- 2) Regulatory Guide 8.13 - Instruction Concerning Prenatal Radiation Exposure  
(<http://www.nrc.gov/reading-rm/doc-collections/reg-guides/occupational-health/active/8-13/index.html> ) (Attachment)

**e. X-Ray Users: Michigan Occupational Safety and Health Administration (MIOSHA)**

- 1) Part 5 Rules - Standards for Protection Against Radiation  
([http://www.michigan.gov/documents/bhs\\_irr\\_part5\\_141982\\_7.pdf](http://www.michigan.gov/documents/bhs_irr_part5_141982_7.pdf))
- 2) Part 13 Rules - Miscellaneous Sources  
([http://www.michigan.gov/documents/bhs\\_irr\\_part13\\_141990\\_7.pdf](http://www.michigan.gov/documents/bhs_irr_part13_141990_7.pdf))

**7.6 Laser Safety**

OU's Laser Safety Program is administered by the Department of EHS with the Laboratory Compliance Manager acting as the University's designated Laser Safety Officer (LSO). The LSO is responsible for ensuring compliance with OU's Laser Safety Manual which was written to

provide guidelines for the safe use of laboratory lasers including proper set up and operation. OU Laser Safety Manual is based on recommendations established by the American National Standards Institute, American National Standard for the Safe Use of Lasers. All users operating Class 2 or higher lasers are included in OU's Laser Safety program.

**a. Laser Safety Services**

- 1) OU's Laser Safety Manual <http://www4.oakland.edu/?id=6087&sid=201>
- 2) Laser Safety Training – (Contact the LSO at extension 4314)

**7.7 Nanomaterial Safety**

Nanomaterial Safety involves the safe use of engineered or synthesized nanomaterials that have at least one dimension in the 1 and 100 nanometers scale. Work involving the use of engineered nanoparticles, (excluding biomolecules such as proteins, carbohydrates, lipids and nucleic acids or polymeric materials) must be reported to the Chemical Hygiene Officer. The National Institute of Safety and Health recognizes the challenges involved in protecting workers against the effects of exposures to nanomaterials especially when the effects of nanomaterials exposure are not well understood. In response to increased University research interest in the areas of nanotechnology research, OU has adopted Nanotechnology Guidelines to protect researchers, ancillary staff, and the environment from exposures to nanomaterials created or used in University laboratories. These guidelines will be updated periodically as new information on the safe use and effects of nanomaterials are known.

**a. Summary of Chemical Hygiene Plan Policy for Engineered Nanoparticles - Nanomaterials (OU's Chemical Hygiene Plan - Section 3.7 See Research Policy – Section 7.4)**

- 1) Liquid Solutions of nanomaterials where there is no potential for aerosol production or potential to be evaporated to a powder form shall be managed according to standard chemical hygiene practices outlined in this Chemical Hygiene Plan.
- 2) Engineered nanoparticle operations may be considered “High Hazard Work.” The Chemical Hygiene Officer must be contacted to provide a “hazard assessment,” and Standard Operating Procedures may be required. Researchers conducting work with engineered nanoparticles must follow guidelines provided in Environmental Health & Safety Fact Sheet: 1, “Nanotechnology: Guidelines for Safe Research,” located in Appendix of this Chemical Hygiene Plan.

**b. Nanotechnology: Guidelines for Safe Research Practices ([Attachment 7j](http://www4.oakland.edu/?id=6140&sid=201))**  
<http://www4.oakland.edu/?id=6140&sid=201>

**7.8 Robotics Safety**

Robots and Robot Systems Safety Guidelines have been written to provide research lab general guidelines for the safe use of Robots and Robot Systems in OU laboratories. The guidelines are based on the American National Standard for Industrial Robots and Robot Systems - Safety Requirements (ANSI/RIA R15.05 -1999). These guidelines will cover all aspects of Robotic research at OU including, manufacturing, remanufacturing, rebuilding, robot safety design and

robot installations. All state and federal standards for Lock Out Tagout, Machine Guarding, and Mechanical Power Transmission Apparatus will also be enforced where applicable.

a. **Robots and Robot Systems Safety Guidelines (Attachment 7k)**  
<http://www4.oakland.edu/?id=6088&sid=201>

b. **Robots and Robot Systems Training**

Contact the Laboratory Compliance Manager at extension 4314 for the following required training:

- 1) Michigan Right to Know training
- 2) Power Lockout Tag-out Training

c. **Applicable Regulations**

- 1) Part 24 - Mechanical Power Presses  
[http://www.michigan.gov/documents/CIS\\_WSH\\_part24\\_34781\\_7.pdf](http://www.michigan.gov/documents/CIS_WSH_part24_34781_7.pdf)
- 2) Control of Hazardous Energy Sources (Lockout/Tagout) (29 CFR 1910.147)  
[http://www.michigan.gov/documents/CIS\\_WSH\\_part85\\_51275\\_7.pdf](http://www.michigan.gov/documents/CIS_WSH_part85_51275_7.pdf)
- 3) Right to Know/Hazard Communication/Retention of DOT Markings, Placards and Labels (29 CFR 1910.1200)  
[http://www.michigan.gov/documents/CIS\\_WSH\\_part\\_42\\_47164\\_7.pdf](http://www.michigan.gov/documents/CIS_WSH_part_42_47164_7.pdf)

## 7.9 Hazardous Waste Management

OU Hazardous Waste Management Program was developed to maintain regulatory compliance, provide cost effective disposal services, and to provide environmental stewardship to the campus community. The Hazardous Waste Management Guidance Manual provides the framework for Hazardous Waste Management at OU, by providing techniques for proper hazardous waste management as well as details on proper labeling, storage, segregation, recycling and waste minimization. Requirements for training, emergency spill response and incident reporting are also detailed in the document.

a. **OU's Hazardous Waste Management Guidelines**

<http://www2.oakland.edu/search/?cx=000773210675483822736:atxvhmj98dy&cof=FORID:9&q=hazardous%20waste%20policy#1165>

b. **Regulations**

- 1) Michigan Department of Environmental Quality
  - Part 111 Hazardous Waste Management  
<http://legislature.mi.gov/doc.aspx?mcl-451-1994-ii-3-111>
  - Part 121 Liquid Industrial Waste  
<http://legislature.mi.gov/doc.aspx?mcl-451-1994-ii-3-121>

- 2) City of Detroit Water and Sewerage Department
  - Article III – Sewers and Drains
    - <http://www.dwsd.org/>.

**d. Training**

- 1) Hazardous Waste Management Training (Contact EH&S at extension 4196)



# Oakland University

## Administrative Policies and Procedures

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Attachment 7a

**NUMBER:** 620

**SUBJECT:** Environmental Health and Safety

**AUTHORIZING BODY:** Vice President for Finance and Administration

**RESPONSIBLE OFFICE:** Environmental Health and Safety

**DATE ISSUED:** May 1997

**LAST UPDATE:** September 2007

**RATIONALE:** To provide information to Oakland University on issues related to occupational and environmental health and safety, and fire and life safety.

**POLICY:** The Office of Environmental Health and Safety (EH&S) is responsible for the development, implementation and management of University policies and procedures that are designed to protect employees from occupational illness/injury, protect campus persons and buildings from fire, protect the University from fines and penalties for failure to comply with environmental health and safety rules and regulations, and protect the environment and surrounding community from injury/illness resulting from improper handling/disposal of hazardous materials on campus.

**SCOPE:** This policy applies to all faculty, staff, students, vendors, contractors and visitors on campus.

**DEFINITIONS: *Authority Having Jurisdiction:*** The governmental agency, subagency or owning authority which regulates processes and compliance.

***Biohazardous Materials:*** Hazardous biological materials which can significantly impact the environment, agriculture, and cause disease to living organisms, including humans, animals and plants. Biohazardous materials include recombinant DNA, infectious organisms (i.e. bacteria, fungi, parasites, prions, rickettsias, viruses, etc.), tissues containing infectious organisms, and biologically active agents (i.e. toxins, allergens and venoms).

***Compliance Program:*** A program which consists of any/all policies and procedures that must be implemented at the University in order to comply with a specific regulation. The program may include documentation, training programs and other educational material.



**Compliance Program Guidance Manual:** *A manual or guidance document that describes in detail the methods that Oakland University will employ in order to comply with relevant regulatory standards. These include, but are not limited to: Biosafety, Bloodborne Pathogens Exposure Control, Chemical Hygiene Plan, Confined Space Entry, Hazard Communication (Michigan-Right-to-Know), Hazardous Waste Management, Medical Waste, Power Lockout, Radiation Safety, Respiratory Protection Program and Tuberculosis Exposure Control.*

**Exit Access:** Refers to building corridors and stairwells leading up to “exits”, whereas “exits” are the doors, or other means provided, that open to areas of safety away from fire and smoke.

**Hazardous Waste:** A waste with properties that make it dangerous or potentially harmful to human health or the environment and/or that exhibits at least one of the following characteristics – ignitability, corrosivity, reactivity, or toxicity. Hazardous wastes can be liquids, solids, contained gases, or sludges and can be the by-products of manufacturing processes or simply discarded commercial products, like cleaning fluids or pesticides.

**Institutional Biosafety Committee:** The use of biohazardous material is governed by the Institutional Biosafety Committee. All proposed use of biohazardous materials must be reviewed and approved by the Institutional Biosafety Committee. Once approved, users of biohazardous material must comply with all applicable rules and guidelines governing the use, storage, transport and disposal of all potential human pathogens. Compliance is then monitored and enforced by the Laboratory Compliance Manager who acts as the University’s Biosafety Officer, and serves as a member of the Biosafety Committee. The Biosafety Officer, under the direction of the Vice Provost for Research, will enforce all aspects of the University’s Select Agent Program per the requirements of the Animal and Plant Health Inspection Service (APHIS)/Centers for Disease Control and Prevention (CDC) rules and regulations.

**Laboratory Safety Committee:** General laboratory activities, including the use of laboratory chemicals, supplies and equipment, are all addressed by the Laboratory Safety Committee. Any/all issues, problems, questions, etc. related to laboratory safety are reviewed by the Laboratory Safety Committee for guidance and consultation. Approval and enforcement authority are the responsibility of the Laboratory Compliance Manager acting as the University’s Chemical Hygiene Officer and Laboratory Safety Committee Chair.

**Occupational Safety Regulation:** *A rule, ordinance, or law by which conduct related to workplace safety is regulated.*

**Office of Environmental Health and Safety:** EH&S is organized into two primary categories of responsibility:

- A. Occupational and environmental safety which includes:
  - 1. Protection of the environment and public health including air, water and land.
    - i. Participation on University Stormwater Pollution Prevention Committee.
  - 2. Hazardous waste management.
- B. Occupational health and life safety which includes:
  - 1. Occupational hazards including employee training, regulatory compliance and industrial hygiene

- i. Chair University Health and Safety Committee
  - ii. Participation on University Pandemic Planning Taskforce
- 2. Fire and life safety.
- 3. Construction safety
- 4. Laboratory safety which includes radiation safety, biological safety and chemical hygiene.
  - i. Chair Laboratory Safety Committee
  - ii. Participation on Radiation Safety Committee
  - iii. Participation on Institutional Biosafety Committee.

**Pandemic Planning Taskforce:** The Committee will address the University's Business Continuity Planning and Infection Control Planning in preparation for a pandemic or other health emergency or any emergency related closure.

**Radiation Safety Committee:** The use of ionizing radiation, including radioisotopes and radiation-generating machines, is governed by the Radiation Safety Committee. All proposed use of ionizing radiation on the University campus must first be reviewed and approved by the Radiation Safety Committee. Once approved, users of ionizing radiation must comply with the Federal, State, University and Radiation Safety Committee rules governing the use, storage, transport and disposal of radioisotopes and radiation-generating machines. Said compliance is then monitored and enforced by the Laboratory Compliance Manager who acts as the University's Radiation Safety Officer and who serves as a member of the Radiation Safety Committee.

**Select Agent Program:** The Centers for Disease Control and Prevention (CDC) regulates the possession, use and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. The Select Agent Program oversees these activities and registers all laboratories and other entities in the United States of America that possess, use, or transfer a select agent or toxin.

**Stormwater Pollution Prevention Committee:** The Committee will address the requirements of the National Pollutants Discharge Elimination System (NPDES) including management of the University's Stormwater Permit Application.

**University Health and Safety Committee:** The Committee will work in conjunction with EH&S to develop a Health and Safety Program for the University. The Committee, through the Chair (The Manager of Environmental Health and Life Safety), will act as an advisory group to the University, will apprise the Administration and make recommendations for the correction or potentially unsafe practices and conditions.

## **PROCEDURES:**

### **A. *Ensuring Regulatory Compliance***

When an occupational safety regulation is deemed applicable to the University's activities and/or conditions, the EH&S staff member shall examine the regulatory text, and generate a Compliance Program which consists of any/all policies and procedures that must be implemented at the University in order to comply with the regulation, and thereby protect University employees. [Note: Occupational safety regulations provide the minimum requirements toward this goal; the EH&S has the right and responsibility to add any reasonable requirements to the Compliance Program as deemed necessary. Each

Compliance Program shall be described in a Compliance Program Guidance Manual (Manual), which is distributed to front-line supervisors, managers, etc., of any/all departments that are impacted by the regulation. EH&S shall also distribute updates to this Manual as often as necessary.

EH&S shall train and test supervisors (and their current employees if so desired by the supervisors) in topics explicitly required by the Compliance Program, in addition to those deemed necessary by EH&S. Supervisory training sessions and tests shall be repeated regularly (at a *minimum* as often as is explicitly required by the regulation).

Once a supervisor has,

1) received the Compliance Program Guidance Manual;

2) completed the training;

3) passed the associated examination; and

4) received training materials and blank exams; the following becomes his/her responsibility (or the responsibility of his/her designee):

- Arranging for funding of any/all materials, supplies, equipment, and so forth, required by the Compliance Program.
- Record-keeping (with copies of any/all records submitted to EH&S upon request).
- Monitoring and enforcing employee compliance; utilizing any/all disciplinary resources allowed whenever employees fail to comply.
- Making arrangements for training and testing of any/all employees within 10 calendar days of employment.
- Coordination of training/ testing of existing employees at the required intervals.
- Submitting photocopies of any/all completed tests to EH&S for grading and database entry. Note: EH&S maintains a master database of all employee training records.
- Bringing to the attention of EH&S in a timely manner any problems, concerns, or questions, related to regulatory compliance or safety in general.

## **B. Emergency Procedure - Fire**

**Fire Alarms** - When an emergency evacuation alarm is sounded in any University building, all persons will **immediately** leave the building in an orderly manner by means of the nearest exit. For those operations that require special consideration, special evacuation plans must be approved by the EH&S and steps immediately initiated to secure the operation and evacuate personnel as soon as is practical.

- **Evacuation** - Under no circumstances are any employees to remain in, or return to, an evacuated building, unless they first secure the permission of the Oakland University Police Department (OUPD), local police or fire officials, and/or an "ALL CLEAR" is issued by the OUPD. Employees who witness unauthorized persons remaining in, or re-entering a building, should bring this to the attention of the OUPD, local police or fire officials.
- **Use of Elevators** - For their own protection, faculty, staff, visitors, students and vendors will refrain from using elevators during an emergency evacuation.
- **Safe Distance** - Emergency responders require all persons to remain at least 100 feet away from evacuated buildings to enable rescue/responding vehicles and personnel to enter and exit the buildings quickly and safely.

## **C. Drills**

EH&S will schedule, monitor, and maintain records of each non-dormitory fire drill as required. University Housing schedules and maintains records of dormitory fire drills as required.

- Every alarm must be treated as an **actual emergency**, University faculty and staffs are directed NOT to call the police dispatcher to determine whether the alarm is a drill.

**D. Use of Exits and Exit Access**

- Employees must never obstruct exit-access (building corridors and stairwells leading up to exits) OR exits (i.e., with furniture, storage, displays, vending machines, etc), and should immediately report any such obstructions they may encounter to EH&S.
- Fire doors on stairwells (unless designed, constructed and installed to close automatically in the event of a fire) are to remain closed at all times and should NEVER be propped open (e.g., with chairs, door-stops, etc.). Any/all “prop-open” devices should be immediately removed.
- Exit signs should be properly illuminated at all times and should not be obstructed or blocked from view. Any obstructive items should be immediately removed when encountered (and/or reported to EH&S).
- Exits or exit-access doors should never be locked (unless the doors are equipped with panic hardware or other approved means to permit emergency egress by building occupants). Violations should be immediately reported to EH&S.

**E. Fire Protection Equipment**

- Tampering with, obstructing or in any way interfering with fire protection equipment, including but not limited to: smoke detectors, pull stations, fire extinguishers, sprinklers, horns and/or strobes is prohibited.
- All fire protection equipment shall be installed in compliance with applicable codes and standards under the supervision of EH&S (or their designee), and must be approved prior to being placed in service.
- Clear access must be maintained at all times to all fire extinguishers, fire alarms, and all other emergency fire equipment. Access should never be blocked to this equipment. Obstructions should be immediately removed and reported to EH&S.

**F. Fire Prevention and Fire Safety Systems**

**1. Codes and Standards**

a. Oakland University recognizes and hereby establishes the use of the following codes and standards related to fire safety:

**1. Classrooms, office buildings, dormitories and places of assembly:**

1. The State of Michigan Department of Consumer and Industry Services, Bureau of Fire Safety and the State Fire Safety Board, through Section 3c of Act No. 207 of the Public Acts of 1941 (which establishes rules that apply to these types of buildings and references additional standards developed by the National Fire Protection Association (NFPA)).

(1) All other buildings at the University must be constructed to the standards established by the most recently adopted edition of the Michigan Construction Code, and should be maintained to the standards established by the NFPA 101 and NFPA 1.

**a. Plans and Specifications**

i. Departments or persons wishing to construct, add to, modify, repair, or remodel any building or portion of a building that may affect the building’s fire protection features or its fire safety systems, may do so only after review and approval by the EH&S and the Facilities Management (FM).

- ii. Departments or persons wishing to install, remove, repair, or modify any fire alarm, fire detection, or fire suppression system may do so only after review and approval by EH&S.
- iii. Detailed plans and specifications for any projects described in 2. a. and 2. b. above must be submitted to and approved by EH&S and FM. Submitted documents will be reviewed to ensure compliance with any/all generally accepted and/or adopted fire code guidelines.
  - 1. Plans and specifications must include: drawings of sufficient detail so that the extent and nature of the work is clearly identified, specifications of the material to be used, and Underwriters Laboratories listings and design numbers as appropriate.

**b. Inspection and Occupancy Approval**

- i. All projects will require a final inspection and approval from EH&S and/or the State or Local Fire Marshall, prior to occupancy and/or the closeout of the project. Projects that involve the concealment of any work will be required to be inspected by the appropriate office or agency prior to any concealment.
- ii. The University Project Manager of each construction project shall either serve as, or formally designate, an individual to handle/coordinate health and safety matters; this individual will act as liaison to EH&S, and arrange for any/all required meetings, submittals, inspections, etc.
- iii. Any work that is found to be in non-compliance, or has not been approved by the appropriate office or agency, must be corrected at the direction of the appropriate office or agency; any/all costs associated with the correction(s) shall be the responsibility of the department that initiated the original project.

**c. Unauthorized Activities and Equipment**

- iii. Cooking, grilling and the use of unapproved cooking appliances are prohibited except in areas designated for such use or with the written approval of the Authority Having Jurisdiction.
- iv. Use of any unauthorized electrical equipment (i.e. space heaters, hot plates, grills) is prohibited.
- v. Open burning, flames and burning of candles or combustibles are prohibited.

**d. Bonfires**

- iii. A bonfire may be allowed only after obtaining a permit from EH&S and in conjunction with an organized event and/or facility rental for a recognized University function.

**G. Laboratory Safety**

- 1. EH&S under the direction and guidance of the three (3) associated Safety committees, provides consultation and operational support to the academic and research community in an effort to maintain a safe and healthful working and learning environment

**2. Laboratory Audits**

- The Laboratory Compliance Manager, acting as Radiation Safety Officer, Biosafety Officer, and Chemical Hygiene Officer, will conduct regular announced and unannounced compliance audits of laboratories.
- 2. Failure to maintain a safe and regulatory compliant working and teaching laboratory environment will result in corrective action, up to and including the closure of the offending laboratory and the revocation of the privilege to use regulated substances at the University.
- It is the responsibility of the Department Chairs, Principal Investigators and Laboratory Managers to ensure that research and teaching labs are free of hazards and in compliance with all applicable regulations and guidelines.

#### **H. Hazardous Waste Management**

- EH&S collects and disposes of hazardous waste in accordance with applicable laws. Hazardous waste may not be collected, disposed of, or stored without prior approval from EH&S. Generally, EH&S will collect and dispose of hazardous waste at no charge to the generating department, except for the following units or waste streams:
  - Auxiliary units disposing hazardous wastes with the assistance of EH&S, will be charged disposal fees.
  - Disposal arrangements and disposal fees for wastes classified as liquid industrial waste by the Michigan Department of Environmental Quality (includes some off-specification commercial chemical products, industrial wastewater, used oil that is being recycled, storm sewer and sanitary sewer clean-out residue, grease trap clean-out residue, and other liquid industrial waste) will be the responsibility of the generating departments. EH&S must be notified prior to disposal.
  - Disposal arrangements and disposal fees for wastes classified as asbestos waste, including asbestos that is abated, remediated, and/or removed will be the responsibility of EH&S or FM. An Asbestos Waste Shipment Record which complies with applicable National Emissions Standards for Hazardous Air Pollutants (NESHAP) Standards and applicable Department of Transportation (DOT) Standards and which documents landfill disposal in an approved landfill must be provided to EH&S.
  - Waste generated by contractors and any waste from remodeling or new construction will be the responsibility of the contractor.
  - A copy of the associated "Hazardous Waste Manifest", listing Oakland University's "Generator ID Number" must be forwarded to the EH&S within five (5) business days of pick-up.
  - All employees (including graduate students and/or student employees) performing tasks in an area where hazardous wastes are generated or stored must receive Hazardous Waste Management training.
- EH&S must be notified of all containers of hazardous waste immediately so that on-site storage and/or disposal can be arranged. Unwanted electrical equipment must be delivered to the University Property Office (Property Office) for recycling unless it is determined that the electrical equipment cannot be decontaminated. A certificate of decontamination must be affixed to any lab equipment delivered to the Property Office. Arrangement must be made for contaminated equipment to be transferred to EH&S or picked-up for disposal as a hazardous waste. A copy of any hazardous waste manifests signed at the time of hazardous waste disposal must be forwarded

to the Laboratory Compliance Manager. All questions concerning hazardous waste disposal should be directed to the EH&S.

#### ***I. Authority***

- The Office of Environmental Health and Safety shall be notified immediately of the arrival of representatives and/or inspectors representing local, state or federal regulatory agencies responsible for environmental and/or occupational health and/or life safety.
- EH&S or their designees may enter premises and other areas owned, rented or leased by the University for the purposes of conducting inspections (announced or unannounced), addressing safety hazards, testing, maintenance or repair of safety equipment, investigation of fires or occupational injuries/illnesses, and/or investigation of health or fire safety concerns, questions, complaints or violations (actual or potential).
- Upon observing a condition or activity out of compliance with one or more University Compliance Programs, and/or one that is otherwise dangerous to persons or property, the EH&S Staff or their designees may take any/all necessary steps to 1) have the hazardous condition/activity abated/terminated, and 2) protect campus persons and property until that time. This could include, but is not limited to, the following:
  - Bringing the matter (verbally or in writing) to the attention of any/all responsible parties (including, but not limited to, the employees immediately involved/impacted, their supervisors, the Deans, Directors or Department Heads).
  - Allowing a reasonable period of time to correct the situation; perhaps requesting that any/all abatement activities/strategies be provided to EH&S following completion.
- Upon observing a condition or activity deemed “immediately dangerous to life or health” (often referred to as an “IDLH situation”) EH&S Staff or their designees have the right and responsibility to shut down whatever operations are impacted/implicated by the hazardous act/condition, and deny access (up to and including padlocking the equipment, area, etc.) to any/all individuals until the situation has been corrected.
- This authority also applies unequivocally to ANY/ALL outside contractors performing work on the University’s campus.

#### **RELATED POLICIES AND FORMS:**

- [Policy 310 – Building Alterations, Renovations and/or Modifications](#)
- [Policy 715 – Employee Injury and Compensation Claims](#)

# Site-Specific Laboratory Safety Training Checklist

Attachment 7b

Employee Name \_\_\_\_\_ Principal Investigator Name \_\_\_\_\_

**ALL** employees of this lab must sign a completed training checklist. **NEW** employees must receive this *site-specific* training within 10 days of transfer/new employment, and **ONLY** perform **supervised** activities until then. Completed checklists should be maintained in the lab.

Safety Topic	Y	N	NA
OSHA requirement of Laboratory "Right-to-Know" Standard training, knowledge and/or experience			
Location of emergency contact names and phone numbers (including Public Safety, EH&S and Lab Personnel)			
Location of the laboratory's Chemical Hygiene Plan			
Location of laboratory personal protective equipment (PPE) and policy for accessing or ordering			
How you should select PPE (criteria to be used)			
<i>Demonstration</i> of properly inspecting, putting on and taking off PPE used in your laboratory			
Limitations (i.e. goggles vs. safety glasses, or life of gloves) of each piece of PPE you shall use in lab			
<i>Demonstration</i> of proper fume hood operation, including qualitative flow check			
Chemicals in lab, and min. volumes thereof, which, if spilled, could create an <b>IDLH*</b> situation			
Response to <b>IDLH*</b> spills, accidents, injuries, illnesses and/or fires (Section 2.7.3.2 and 2.9 in the CHP)			
Response to <b>non-IDLH*</b> spills, accidents, injuries, illnesses and/or fires (e.g. contact personnel, forms, first-aid policy)			
Location of nearest fire extinguisher and fire blanket ( <i>cross out blanket if lab does not contain one</i> )			
Circumstances under which you should decide to use fire extinguisher (e.g. knowledge, experience, fire in escape path)			
Location and <u>proper use</u> of laboratory spill kit			
Location of nearest eyewash station; <i>demonstration</i> of how to activate/use it, and contact lens precautions			
Location of nearest safety shower(s); description of how to activate it and use it			
Laboratory policy with regard to room security (e.g. key policy), supervision and visitors			
Location of MSDS poster, MSDSs and/or other chemical safety reference materials			
Example of MSDS reviewed for format, language, acronyms, and method(s) of applying to lab setting			
Methods of handling non-biohazardous glass waste in the lab (including location of receptacle)			
Methods of handling, labeling and storing chemical waste in the lab			
Examples of laboratory chemicals in each of the following hazard classes (circle those that apply): compressed gas; corrosive; flammable; acute, chronic or reproductive toxicity; reactive; oxidizer; peroxide			
Identification of unusually high hazard chemicals or operations in laboratory; location of written SOP for each			
<b>If you handle bloodborne pathogens, confirmation that you have received Bloodborne Pathogens training from the Office of EH&amp;S, or that arrangements have been made to do so within 10 days</b>			
<b>If you handle radioactive materials, confirmation that you have received Radiation Safety Training from the university's Radiation Safety Officer, or that arrangements have been made to do so within 10 days</b>			

**\*IDLH = Immediately Dangerous to Life or Health**

I hereby certify that all applicable safety items above have been presented, discussed, and demonstrated (as necessary) by my lab supervisor or his/her designee **for every lab I shall be using**. I further certify that I UNDERSTAND the information as it was presented, and should one or more items be unclear in the future, I will ask questions of my lab supervisors (or designees) before proceeding with the operation(s) in question. **I also acknowledge the need to understand response procedures for IDLH incidents before any work in this laboratory begins.**

**Trainer Name (Printed)** \_\_\_\_\_ **Trainer Signature** \_\_\_\_\_  
**Primary Lab Rm #** for which this info was presented \_\_\_\_\_ Will you be working intermittently in **other labs** for which this info was presented? **Y N**



Employee Signature \_\_\_\_\_  
 rev (1/99)

Date \_\_\_\_\_

**Attachment 7c**

**LABORATORY SAFETY AUDIT CHECKLIST**

Date: \_\_\_\_\_ Auditor: \_\_\_\_\_ Room/Bldg: \_\_\_\_\_

Department: \_\_\_\_\_ P.I./Prof: \_\_\_\_\_ Ext. \_\_\_\_\_

Lab employee: \_\_\_\_\_

<b>GENERAL SAFETY/MAINTENANCE- <math>\sqrt</math></b>	<b>Y</b>	<b>N</b>	<b>NA</b>
1. Copy of <i>Chemical Hygiene Plan</i> available in laboratory			
2. All staff trained in proper a) handling of haz mtl; b) storage of haz mtl; and c) disp of haz waste (incl drain) [EH&S Lab Safety training satisfies this requirement, but alternate <i>formal</i> education/training is acceptable]			
3. "Site-specific Training Checklists" completed for all lab staff (including professors/TAs in teaching labs)			
4. Common Use Labs ONLY: All employees in the lab can produce a copy of their completed "Site-specific Training Checklists" (completed forms should be housed in employees' "primary" labs)			
5. Common Use Labs ONLY: Posted with "Visitor Instructions" sign			
6. Laboratory door locked when lab is not in use			
7. Employees are aware of location of (and procedure for obtaining) department's first aid kit			
8. Spill kit(s) available in laboratory <u>or</u> employees know how to access during reg hrs <u>and</u> after hrs.			
9. Laboratory workers have been trained in how to use that lab's or department's spill kit(s)			
10. Hoses used for Bunsen burners are in good condition			
11. MSDS location(s) sign posted			
12. Other signs properly posted (e.g. lasers, toxic chemical storage areas etc.)			
13. Sink drains clean and unobstructed			
14. Generally good housekeeping (e.g. unobstructed aisles, floor clean and dry)			
15. Appropriate waste receptacles for (non-biohazardous) broken glass provided			
16. All electrical appliances properly grounded			
17. Electrical wires free from tangling, obstructing aisles and corroding			
18. Fans, pumps and motors have guards			
19. Lighting levels provide good illumination in all walking, working and service areas			

20. COMMENTS:

<b>SAFETY EQUIPMENT</b>	<b>Y</b>	<b>N</b>	<b>NA</b>
21. Unobstructed eyewash and safety showers; labeled and identified			
22. Eyewash and safety shower flow tested in past year (date of test _____)			
23. Biosafety cabinets properly functioning and certified in past year (date of certif _____)			
24. Goggles available at entrance to lab and provided to visitors upon entering			
25. Personal protective equipment available, used and in good condition (e.g. goggles, gloves)			

26. COMMENTS

<b>GAS CYLINDERS</b>	<b>Y</b>	<b>N</b>	<b>NA</b>
27. Gas cylinders properly labeled with the name of contents			
28. Compressed gas cylinders (whether full or empty) secured			
29. Flammable gas cylinders equipped with flame arrestors			
30. Incompatible gas cylinders kept segregated			
31. Protective caps in place on cylinders which are not in use			

32. COMMENTS:

<b>CHEMICAL SAFETY</b>	<b>Y</b>	<b>N</b>	<b>NA</b>
33. Flammable liquid containers do not exceed limitations for Class.			
34. No more than 10 gallons of flammable liquids are stored outside of safety cans or cabinets			
35. No more than 60 gallons of flammables in a flammable storage cabinet			
36. Approved "flammables" refrigerators used for cold storage of flammable liquids			
37. Flammables stored at least 18" away from ignition sources			
38. Flammables stored away from exits			

39. Structural barriers separate flammables from oxidizers and/or corrosives				
--	--	--	--	--

**LABORATORY SAFETY AUDIT CHECKLIST**  
(Continued)

Date: \_\_\_\_\_ Auditor: \_\_\_\_\_ Room/Bldg: \_\_\_\_\_  
 Department: \_\_\_\_\_ P.I./Prof: \_\_\_\_\_ Ext.: \_\_\_\_\_

40. Chemical containers are in good condition				
41. Chemical containers kept closed when not in use				
42. Chemicals not currently in use are stored away from chemicals being used				
43. Expired, deteriorated or disused chemicals eliminated from stock; placed into hazardous waste area				
44. Glass containers of flam and corrosive chems (> 6 M) stored off of floor AND on shelves below 5 ft.				
45. Chem. containers labeled with hazards; short-term (<1 day) containers labeled with names				
46. Highly/moderately chronic and highly acute toxics labeled; stored in <u>separate labeled areas</u>				
47. Chemicals stored to ensure that they are resistant to sliding falls and/or spills				
48. Chemicals and food stored/handled separately; no evidence of food waste in lab trash cans				
49. Incompatibles stored separately				
50. Light reactives (e.g. hydrogen and chlorine) stored away from light				
51. Water reactives (e.g. sodium, potassium, lithium) stored away from sinks and pipes				
52. Peroxidizable chemicals (e.g. ethers) have dates of receipt AND opening; Container was opened OR peroxide strip testing was performed within six months of today's date				
53. Picric acid is hydrated				
54. COMMENTS:				

<b>CHEMICAL FUME HOODS</b>	<b>Y</b>	<b>N</b>	<b>NA</b>
55. Hoods are uncluttered; all chemicals stored in hood are located near rear of the hood			
56. Long-term <u>storage</u> of chemicals (and/or "air disposal" thereof) in fume hoods is prohibited			
57. Fume hood velocities have been tested in the past year (date of test: _____ )			
58. COMMENTS:			

<b>FIRE PREVENTION/SAFETY</b>	<b>Y</b>	<b>N</b>	<b>NA</b>
59. Lab personnel aware of fire alarm pull station location(s)			
60. Location of nearest fire exiting, known; ext. is fully charged (date of last charge ).			
61. Fire cans (if present) <u>contain</u> fire blankets			
62. All exits maintained to provide free and unobstructed exit			
63. Lab personnel familiar with emergency response procedures (including evacuation plan)			
64. Sign on door alerting fire fighters that lab contains greater than 2 gallons of flammables			
65. Emergency contacts and phone numbers posted on door and telephone			
66. Storage of combustibles, e.g. cardboard boxes and paper towels is minimized			
67. COMMENTS:			

# LABORATORY SAFETY AUDIT CHECKLIST

(Continued)

## ONLY COMPLETE THIS PAGE IF THERE IS HAZARDOUS WASTE BEING STORED IN LABORATORY

Date: \_\_\_\_\_ Auditor: \_\_\_\_\_ Room/Bldg: \_\_\_\_\_  
 Department: \_\_\_\_\_ P.I./Prof: \_\_\_\_\_ Ext.: \_\_\_\_\_

HAZARDOUS WASTE	Y	N	NA
68. All hazardous waste containers are tightly capped (unless waste is being added or removed)			
69. All hazardous wastes are chemically compatible with their containers			
70. All hazardous waste containers are labeled with "Hazardous Waste" labels; and are these labels are completed in-full and correctly			
71. Secondary containment is in place for highly hazardous waste			
72. Hazardous waste containers are in good condition?			
73. Hazardous waste containers are stored in separate areas from hazardous materials currently being used			
74. Staff know and understand how to arrange for hazardous waste to be removed semi-annually by EH&S			
75. Those responsible for that lab's hazardous waste management have received "Hazardous Waste Management" training from EH&S OR from a trained member of that department?			
76. Comments:			

# Oakland University Radioisotope Usage

Page \_\_\_\_\_

Radionuclide: \_\_\_\_\_ Physical/Chemical form: \_\_\_\_\_ Lot#: \_\_\_\_\_ PO#: \_\_\_\_\_  
 Initial Activity Received ( $\mu\text{Ci}$ ): \_\_\_\_\_ Reference Date: \_\_\_\_\_ dpm Date Received: \_\_\_\_\_  
 Source container swipe (dpm above background) \_\_\_\_\_ Date Received: \_\_\_\_\_  
 Packaging (Survey/Swipe \_\_\_\_\_ dpm) / Disposed of by \_\_\_\_\_ on \_\_\_\_\_ (Date)

Date of Usage	Usage				Disposal							
	User Name	Dilution of Stock	Volume Used ( $\mu\text{L}$ )	Quantity Used ( $\mu\text{Ci}$ )	Quantity Remaining ( $\mu\text{Ci}$ )	Solid		Liquid		Drain		Total Disposal ( $\mu\text{Ci}$ )
						Solid Disposal ( $\mu\text{Ci}$ )	Date of Disposal	Liquid Disposal ( $\mu\text{Ci}$ )	Date of Disposal	Drain Disposal ( $\mu\text{Ci}$ )	Date of Disposal	

Page \_\_\_\_\_

Room: \_\_\_\_\_ Building: \_\_\_\_\_

**AREA SWIPE TESTS/SURVEYS****Maintain your counter print-outs and a map of the “Areas” referenced below in your Logbook at all times**

Survey Meter Used \_\_\_\_\_ SN \_\_\_\_\_ Counting Efficiency \_\_\_\_\_

Liquid Scintillation Counter Used \_\_\_\_\_ SN \_\_\_\_\_ Counting Efficiency \_\_\_\_\_

Indicate Testing Procedure Used (include channel number/isotope and count time): \_\_\_\_\_

Line #	Date	Indicate End-of-Day; End-of-Week; or End-of-Month (see *below)	Tester	Isotope(s)	Area # Begin with “Background” for each Date  Include Floors: Indicate Area # “Floor”	Area Meter/Swipe (see *below)		Decontamination Necessary (Y/N)  If Yes, attach sheet referencing the line#, indicating decontamination procedures, and results following decontamination.
						mR/h	dpm	

\*End-of-Day surveys are required in area where radionuclides are in active use. [NOTE: for those using isotopes that cannot be detected by a survey meter (e.g.  $^{14}\text{C}$  and  $^3\text{H}$ ), swipe tests are required.]

\*End-of-Month surveys AND swipe tests are required in areas where small quantities (<200  $\mu\text{Ci}$ ) are used OR

stored. Storage areas include refrigerators, lab shelves, cupboards etc.

\*End-of-Week surveys AND swipe tests are required in areas where, large quantities ( $>200 \mu\text{Ci}$ ) are used.

## Record of Prior Training and Experience

**All sections must be completed before named person may begin duties in radioisotope area. Return original form to the Radiation Safety Officer; keep copy in Radiation Safety Logbook.**

Name: \_\_\_\_\_ Grizz. ID: \_\_\_\_\_  
 Title (Technician, Research Assistant, etc.): \_\_\_\_\_ Birth Date: \_\_\_\_\_  
 Permit Holder/Supervisor: \_\_\_\_\_ Department: \_\_\_\_\_  
 Isotope Labs (Building and Room): \_\_\_\_\_ Phone: \_\_\_\_\_  
 Office (Building and Room): \_\_\_\_\_ Phone: \_\_\_\_\_  
 Email Address: \_\_\_\_\_

### **Prior Training and Experience (Attach additional sheets if necessary)**

<b>Training Topic</b>	<b>Where Trained</b>	<b>Duration of Training</b>	<b>On-The - Job</b>	<b>Formal Course</b>	<b>Description/Title</b>
Principles and practices of radiation practice			Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Radioactivity measurement, standardization, and monitoring techniques and instruments			Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Mathematics and calculations basic to use and measurement of radioactivity			Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Biological effects of radiation			Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	

### **Previous Isotope Handling Experience**

<b>Isotope</b>	<b>Maximum Activity Handled</b>	<b>Where Experience was Gained</b>	<b>Duration of Experience</b>	<b>Type of Use</b>

### **To be Read and Signed by Trainee (Named Individual)**

The representations made by me on this form are true and accurate to the best of my knowledge and recollection. I give permission for Oakland University to contact and obtain training information from any and all sources above.

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

OU-RSC form 101 Tb (09/03)

## Record of Research –Specific Training Conducted by P.I.

**To be completed before individuals may begin duties in radioisotope area.  
Return Original to the Radiation Safety Office; Keep copy in Radiation Safety Logbook**

<b>Permit Holder/Supervisor:</b>	
<b>Department:</b>	
<b>Date and location of Training:</b>	
<b>University Mail Address:</b>	<b>Phone Ext:</b>
<b>Email Address:</b>	

### Topics Covered (Attach additional Sheets if necessary)

- A. Radiation safety considerations of radionuclides used in laboratories. [Should include: physical properties (half-life, radiation emitted, energy of radiation, maximum range of beta particles, etc.), radiation biology (critical organ, toxicity, maximum body burden, bioassays required, etc.) and health physics (survey techniques, shielding any special safety/handling considerations, etc.)]
- B. Use of *Radiation Safety Logbook* and all required records for each isotope used, and the required daily, weekly, monthly and quarterly surveys.
- C. Proper swipe techniques, LSC usage (with quench curve calculations), and Geiger counter usage, including conversion of counts to disintegrations/minute (DPM) and DPM to curies.
- D. Location of all storage areas and any special precautions (especially in shared storage areas) including shielding, etc.
- E. Location of all work areas and any special precautions (especially in shared work areas) including shielding, etc.
- F. Proper waste disposal for isotopes used.

### To be completed by Permit Holder:

In my opinion, the individuals named on the attached sheet have adequate training and experience to safely perform his/her duties involving radioisotopes under my supervision.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_



**To be Read and Signed by Each Trainee (Named Individual)**

I have been presented the training topics as outlined on the attached sheet and have read the written materials provided. I have been given the opportunity to ask questions, and understand that I may contact the Radiation Safety Office if I require further information.

<b>Name:</b>	<b>Date:</b>
<b>Job Title:</b>	<b>Comments:</b>
<b>SS#:</b>	
<b>Signature:</b>	

<b>Name:</b>	<b>Date:</b>
<b>Job Title:</b>	<b>Comments:</b>
<b>SS#:</b>	
<b>Signature:</b>	

<b>Name:</b>	<b>Date:</b>
<b>Job Title:</b>	<b>Comments:</b>
<b>SS#:</b>	
<b>Signature:</b>	

<b>Name:</b>	<b>Date:</b>
<b>Job Title:</b>	<b>Comments:</b>
<b>SS#:</b>	
<b>Signature:</b>	

<b>Name:</b>	<b>Date:</b>
<b>Job Title:</b>	<b>Comments:</b>
<b>SS#:</b>	
<b>Signature:</b>	

Department of Environmental  
**Health and Safety**  
 Oakland University  
 Rochester, MI 48309  
 Phone: 248 370-4196  
 Fax: 248 370-4376

**Attachment 7h**

## RADIOACTIVE MATERIAL TRANSFER AND/OR SHIPMENT FORM

(PRIOR APPROVAL MUST BE OBTAINED FROM ENVIRONMENTAL HEALTH AND SAFETY)

**FROM:** Name: \_\_\_\_\_ N.R.C. License #: 21-10725-03

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

**TO:** Name \_\_\_\_\_ N.R.C. License #: \_\_\_\_\_ Type: \_\_\_\_\_

Address: \_\_\_\_\_ Phone: \_\_\_\_\_

### RADIOACTIVE MATERIAL DESCRIPTION AND MONITORING RESULTS

Monitored By: \_\_\_\_\_ Date: \_\_\_\_\_ Instrument: \_\_\_\_\_

Isotope	Chemical and/or Physical Form	Activity (Millicuries)	Container Description	Radiation (mR/hr)		Smear Test Results (dpm)
				Contact	1 Meter	

MODE OF TRANSFER OR SHIPMENT:      COMMERCIAL CARRIER [    ] SELF [    ]

EXPLAIN:

EH&S Approval Date: \_\_\_\_\_ Signed: \_\_\_\_\_

Originator Date: \_\_\_\_\_ Signed: \_\_\_\_\_

Receiver Date: \_\_\_\_\_ Signed: \_\_\_\_\_

## Application to Use Radiation at Oakland University

**Please Check One:**

- New Permit Application  
 Renewal of Existing Permit  
 Amendment of Existing Permit

### Instructions for New Permit Applicants

The Principal Investigator must submit one copy of a completed application to the Radiation Safety Officer prior to use of radioactive material. The application must be signed by both the Principal Investigator and the Department Chair or Institute Director. The Radiation Safety Committee will review the application and the Radiation Safety Officer will conduct a New Permit Holder Orientation prior to issuing Permit.

### Instructions for Renewal of Existing Permit

A copy of the existing Permit will be given to each Permit Holder at least 30 days prior to Permit expiration. Please review the existing Permit, as regulatory changes may require some sections to be updated even if no change in use protocol has occurred. The completed renewal must be signed by the Principal Investigator and the Department Chair or Institute Director, and the original signed copy of the amendment must be submitted to the Radiation Safety Officer. The Radiation Safety Committee will review the renewal prior to extending the existing Permit.

### Instructions for Amendment of Existing Permit

Additions of new radionuclides, new use protocols, new radiation-generating equipment or new work locations require the submission of an updated application. The completed amendment application must be signed by the Principal Investigator and the Department Chair or Institute Director, and the original signed copy of the amendment must be submitted to the Radiation Safety Officer. The Radiation Safety Committee will review the application prior to amending the existing Permit.

Additions of new chemical forms of approved radionuclides for use in approved protocols may be submitted directly to the Chair of the Radiation Safety Committee in memo form for review. Interim approval may be granted at the discretion of the Chair prior to review by the full Committee. The Chair has the option of requesting the submission of a completed amendment application to the Committee.

I certify that all of the information included on this application is correct and complete to the best of my knowledge. Further, I agree to abide by the rules and regulations of the United States Nuclear Regulatory Commission, the Michigan Department of Community Health – Radiation Safety Section, and the Oakland University Radiation Safety Committee for the proper use, storage and disposal of all radioactive materials and radiation-generating machines.

Signed: \_\_\_\_\_ Date: \_\_\_\_\_  
Principal Investigator

As Department Chair or Institute Director:

- 1) I acknowledge that the above Principal Investigator is working with radioactive materials or radiation-generating machines, and
- 2) I understand that Oakland University's NRC Material License requires that Department Chairs and Institute Directors be responsible for all shared or common work and storage areas.

I agree to accept this responsibility for ensuring that all researchers using shared or common work and storage areas abide by the rules and regulations of the United States Nuclear Regulatory Commission, the Michigan Department of Community Health – Radiation Safety Section, and the Oakland University Radiation Safety Committee for the proper use, storage and disposal of all radioactive materials and radiation-generating machines in these common areas.

By crossing out part two above, no shared or common work or storage areas will be permitted in my Department or Institute.

Signed: \_\_\_\_\_ Date: \_\_\_\_\_  
Department Chair or Institute Director

**1. Applicant Information**

Name: \_\_\_\_\_ University Title: \_\_\_\_\_

Department: \_\_\_\_\_ Office Building/Room: \_\_\_\_\_ Office Phone: \_\_\_\_\_

Home Address: \_\_\_\_\_

Phone: (home) \_\_\_\_\_ (cell) \_\_\_\_\_ E-Mail: \_\_\_\_\_

**2. Radiation Proctor Information**

Name: \_\_\_\_\_ University Title: \_\_\_\_\_

Department: \_\_\_\_\_ Office Building/Room \_\_\_\_\_ Office Phone \_\_\_\_\_

Home Address \_\_\_\_\_ Home Phone \_\_\_\_\_

Phone: (home) \_\_\_\_\_ (cell) \_\_\_\_\_ E-Mail: \_\_\_\_\_

3a. List all open-source radionuclides to be used. Please use a separate line for each chemical form and list all activities in millicuries (mCi). Attach additional sheets if necessary.

Radionuclide	Chemical Form	Order and Transfer Limit	Possession Limit	Maximum Activity Per Experiment	Annual Order and Transfer Limit

3b. Please list anticipated drain disposal activities for each radionuclide.

Radionuclide	Daily Limit (mCi)	Annual Limit (mCi)

3c. List all radiation-generating machines to be used.

Michigan Registration #	Location	Manufact.	Model	Type (EM, x-Ray, etc.)	Mx kVp	Max mA	# of Tubes

3d. Please list all sealed radioactive sources to be used (including “button” sources).

Radionuclide	Activity (mCi)	Assay Date	Manufacturer	Serial Number	Location	Neutron Source?

4. Please list each individual who will be working with radioactive material or radiation generating machines under this Permit.

Name	Date of Birth	Job Title	RSO Training Complete?	Scheduled for RSO Training?

5. Please list each location where open-source radioactive material will be used or stored under this Permit. Please submit a Swipe map for each location listed.

Building and Room	Radionuclides	Room Designation/Use

6. Please describe your proposed use of each radionuclide and each chemical form. A “Radionuclide Protocol Cover Form,” must precede each protocol. Follow the instructions outlined on the Radionuclide Protocol Cover Form.

7. Will you routinely receive radioactive material from individuals or institutions in transactions not requiring a University purchase order?

8. Will you routinely send radioactive material to individuals or institutions outside of Oakland University?

9. Will live animals be used in any radiation protocol?

10. Will biohazardous material be used in any radiation protocol?

11. Will any radiation protocol use or generate vapors, powders or gasses?

12. Shielding (Check all applicable boxes)

Material	Benchtop	Hood / Storage	Waste Container
Plexiglas			

13. Please list all portable contamination survey meters and probes.

Make	Model	Serial Number	End Window	Side Window	Pancake	LEG	Location	Calib. Date

14. Please list location of scintillation counter or gamma counter

Counter Type	Location

15. Will millicurie quantities of energetic beta emitters be used or stored at any time?

16. Please check appropriate boxes for each waste form anticipated to be produced through use of each radionuclide. Check appropriate box even if waste will be diluted and drain disposed, rinsed and disposed of as regular trash, or disposed of as deregulated waste.

Radionuclide	Dry Solid	Aqueous Liquid	Organic Liquid	Scintillation Cocktail	Scintillation Vials	Animal Carcasses

**Radiation Safety Committee Review**

Radionuclide	Protocol	Approved	Disapproved	Expiration

## **Radionuclide Protocol Cover Form**

1. Give the title of the protocol and describe the scientific purpose.
  - a. Title:
  - b. Scientific Purpose:
2. Radionuclide(s) to be used:
3. Radionuclide storage locations:
4. Location where experiment will be conducted:
5. List all shared space/equipment which will be used in the procedure:
6. Have lab workers been trained to conduct this procedure?
7. Estimate how much activity will be used and estimate how it will be disposed:

Total Activity ( $\mu\text{Ci}$ ) used in experiment	Estimated Activity Disposed (microcuries)		
	Dry or Solid	Liquid (not including drain)	Drain Disposal (If applicable)

8. Attach a description of this protocol. (**This cannot be copied from a paper or grant proposal or a book etc.**).
  - a. Your description should focus on containment and safety of radioactive material.
  - b. Every step that involves handling of radioactive substances should be clearly described. Particular attention should be given to steps that involve (i) handling (ii) transfer of radioactive material between containers, (iii) disposal of solutions.
  - c. In each step of the protocol, describe the labware that comes in contact with radioactivity, and specify whether disposable or permanent (reusable) items.
  - d. Describe procedures for decontamination for each.
  - e. Specify in the protocol the amount of radioactivity that is used on average in a single experiment.
  - f. Write an educated estimate for the amount (in micro-curies) of the waste that is produced during major steps that involve disposal. (See example protocols)





# Environmental Health & Safety

## Fact Sheet: 1

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### **Nanotechnology: Guidelines for Safe Research Practices**

#### **Introduction**

This fact sheet provides environmental, health and safety information to Oakland University researchers working with engineered nanoparticles. In general, this does not include biological (biomolecules such as proteins, carbohydrates, lipids and nucleic acids) or polymeric materials. This Fact sheet should be incorporated as a standard operating procedure in each laboratory's chemical hygiene plan. Given the evolving knowledge base regarding potential health effects of nanoparticles, this fact sheet may be updated.

Nanoparticles are particles that have at least one dimension between 1-100 nanometers. Particles in this size range have always been present in Earth's air. Nanoparticles may be naturally occurring (such as in volcanic ash), produced as unintentional byproducts (such as in auto emissions) or intentionally created or engineered. These very small particles often possess different properties than larger particles of the same composition, making them of interest to researchers and of potential benefit to society. This fact sheet focuses on lab practices researchers should follow to protect themselves from the potential hazards of engineered nanoparticles.

Nanoparticles can be spheres, rods, tubes, and other geometric shapes. The small particles may be bound to surfaces or substrates, put into solution or suspension, attached to a polymer, or in a few cases handled as a dry powder.

Various nanoparticles can be created in the laboratory under experimental procedures, and some can be purchased from commercial vendors. In most research, the amount of material used is small, generally less than a gram.

Only limited information is currently available on the toxicity of many nanoparticles. It is believed that some engineered nanoparticles may present health effects following exposure, based in part on air pollution studies that show smaller particles get deep into the lungs and can cause human illness. However, laboratory research most commonly involves handling nanoparticles in liquid solutions or other forms that do not become easily airborne, and even free formed nanoparticles tend to agglomerate to a larger size.

When research involves work with engineered nanoparticles for which no toxicity data is yet available, it is prudent to assume the nanoparticles may be toxic, and to handle the nanoparticles with precaution using the laboratory safety techniques outlined below.

### **Potential Routes of Occupational Exposure to Researchers**

There are four possible routes of workplace exposure to nanoparticles: inhalation, ingestion, skin absorption, and injection.

**Skin absorption:** In some cases nanoparticles have been shown to migrate through skin and be circulated in the body. If the particle is carcinogenic or allergenic, even tiny quantities may be biologically significant. Skin contact can occur during the handling of liquid suspensions of nanoparticles or dry powders. Skin absorption is much less likely for solid bound or matrixed nanomaterials. Researchers should wear gloves to protect themselves from skin absorption, and to protect their research materials from being contaminated.

**Ingestion:** As with any particulate, ingestion can occur if good hygiene practices are not followed. Once ingested, some types of nanoparticles might be absorbed and transported within the body by the circulatory system. To prevent ingestion, eating and drinking are not allowed in laboratories outside of designated areas. Also, spills of nanoparticles should be quickly and properly cleaned up, as detailed below.

**Inhalation:** Respiratory absorption of airborne nanoparticles may occur through the mucosal lining of the trachea or bronchioles or the alveolus of the lungs. Because of their tiny size, certain nanoparticles appear to penetrate deep into the lungs and may translocate to other organs following pathways not demonstrated in studies with larger particles. Thus, whenever possible, nanoparticles are to be handled in a form that is not easily made airborne, such as in solution or on a substrate,

**Injection:** Exposure by accidental injection (skin puncture) is also a potential route of exposure, especially when working with animals or needles. To prevent this, wear gloves and lab coats, and apply the standard practices for working with sharps.

### **Laboratory Safety Guidelines for Handling Engineered Nanoparticles**

The current practices for working with engineered nanoparticles safely are essentially the same as one would use when working with any research chemical of unknown toxicity.

1. Use good general laboratory safety practices as stated in your chemical hygiene plan. Wear double gloves (preferably nitrile gloves), safety glasses, and appropriate protective clothing.
2. All personnel participating in research involving nanoscale materials need to be briefed on the potential hazards of the research activity, as well as on proper techniques for handling nanoparticles. The contents of this Fact Sheet can serve as a useful component of this training. As with all safety training, written records need to be maintained to indicate who has been trained on this topic.
3. Eating and drinking are allowed only in designated areas where chemicals or nanoparticles are not used.
4. When purchasing commercially available nanoscale materials, be sure to obtain the Material Safety Data Sheet (MSDS) and to review the information in the MSDS with all persons who will be working with the material.

5. In some cases, the making of nanomaterials involves the use of chemicals that are known to be hazardous or toxic. Be sure to consider the hazards of the precursor materials when evaluating the process hazard or final product. Users of any chemicals should make themselves familiar with the known chemical hazards by reading the MSDS or other hazard literature.
6. To minimize airborne release of engineered nanoparticles to the environment, nanoparticles are to be handled in solutions, or attached to substrates so that dry material is not released. Where this is not possible, nanoscale materials should be handled with engineering controls such as a HEPA-filtered local capture hood or glove box. If neither is available, work should be performed inside a laboratory fume hood. HEPA-filtered local capture systems should be located as close to the possible source of nanoparticles as possible, and the installation must be properly engineered to maintain adequate ventilation capture.
7. Use fume exhaust hoods to expel any nanoparticles from tube furnaces or chemical reaction vessels. Do not exhaust aerosols containing engineered nanoparticles inside buildings.
8. If you must work outside of a ventilated area with nanomaterials that could become airborne, wear a respirator with NIOSH-approved cartridges that filter particles. EH&S will work with researchers to provide the most appropriate type of respirator. Contact the Office of Environmental Health and Safety ( 370-4314) for information on respirator use.
9. Equipment used to create or handle nanoscale materials should be cleaned or evaluated for potential contamination prior to disposal or reuse.
10. Laboratory equipment and exhaust systems should be evaluated prior to repair, remodeling or removal and construction/maintenance crews need to be alerted to the potential exposure to nanoparticles. Contact EH&S for assistance with this notification.
11. Spills of engineered nanoparticles are to be cleaned up right away. The person cleaning up should wear gloves and either vacuum up the area with a HEPA filtered vacuum or wet wipe the area with towels, or combination of the two. For spills that might result in airborne nanoparticles, proper respiratory protection should be worn (see item 8 above). For assistance with cleaning up any chemical spill contact EH&S.
12. Dispose of and transport waste nanoparticles in solution according to hazardous waste procedures for the solvent. All waste engineered nanoparticles should be treated as unwanted hazardous "toxic" materials unless it is known to be non-hazardous. If you have questions on how to dispose of a specific nanoparticle waste, call EH&S for more information.

### **Additional Information**

For more information on Health and Safety of Nanotechnology visit the following web sites:

NIOSH (<http://www.cdc.gov/niosh/topics/nanotech/>)

National Nanotechnology Initiative (<http://www.nano.gov/>)

EPA (<http://www.epa.gov/oppt/nano/nano-facts.htm>)

Woodrow Wilson International Center for Scholars (<http://nanotechproject.org/>)

For any questions on this Fact Sheet, please contact the Laboratory Compliance Manager at 370-4314. This fact sheet was adapted with permission from the University of California, Berkeley, Office of Environmental, Health and Safety, Fact Sheet Number 73.

## Robots and Robot Systems Safety Guidelines

1. **Introduction:** These Robots and Robot Systems Safety Guidelines have been written to provide research lab general guidelines for the safe use of Robots and Robot Systems in Oakland University laboratories. The guidelines are based on the *American National Standard for Industrial Robots and Robot Systems - Safety Requirements (ANSI/RIA R15.05 -1999)*. These guidelines will cover all aspects of Robotic research at Oakland University including, manufacturing, remanufacturing, rebuilding, robot safety design and robot installations. All state and federal standards for Lock Out Tagout, Machine Guarding, and Mechanical Power Transmission Apparatus will also be enforced where applicable.
  
2. **Robots and Robotic System Safety Responsibilities:** The responsibility for compliance with robot and robot system safety is shared by Oakland University's Environmental Health and Safety (EH&S), the Department Chairs, the Laboratory Supervisor and the Laboratory employees.
  - 2.1. **Environmental Health and Safety:** EH&S is responsible for interpreting federal, state, and local regulations relating to robot and robot system safety used in laboratory teaching and research. The primary function of EH&S is to act in an advisory capacity to the individual department supervisors/administrators, and help them provide a safe workplace. EH&S services include :
    - 2.1.1. Conducting Laboratory Audits
    - 2.1.2. Consulting with employees regarding robot and robot system safety.
  - 2.2. **Oakland University Department Personnel:** Each of the following departments is known to operate robots or robot systems and will implement the guidelines set forth in the Robot and Robot System Safety Plan.
    - 2.2.1. School of Engineering and Computer Science
  - 2.3. **Department Heads:** Department Chairs are responsible for implementing university regulations within their departments and therefore will be responsible for ensuring implementation of the Robot and Robot Systems Safety Guidelines within their department.
  - 2.4. **Robotics Laboratory Supervisor:** The Principle Investigator or Supervisor for the Robotics Laboratory will be responsible for adherence to the Robot and Robot Safety Guidelines and will be responsible for implementing the guidelines for their lab. For shared laboratories this responsibility will be delegated by the Department Chair to a person within the Chairs department. Robotics Laboratory Supervisor will have the following responsibilities:
    - 2.4.1. **General Knowledge and Preparedness of Robot and Robot System Safety**
      - 2.4.1.1. Selects and employs work practices and engineering controls that prevent injury to staff.
      - 2.4.1.2. **Defines hazardous operations, designates safe practices and selects protective equipment.**

- 2.4.1.3. **Prepare written Standard Operating Procedures (SOP's) for all robot and robot systems.**
  - 2.4.1.3.1. **SOP's will be include safety procedures for the various end effectors, hazardous materials and auxiliary devices that will be used.**
  - 2.4.1.3.2. **SOP's will be updated with any change in the robot, robot system, end effector, hazardous materials, auxiliary devices or process change.**
- 2.4.1.4. Ensures appropriate (engineering and personal protective equipment) controls are in good working order.
- 2.4.1.5. Make copies of the Robot and Robot System Safety Guidelines available to the laboratory employees, students and support staff.
- 2.4.2. Employee training and supervision:**
  - 2.4.2.1. Ensure that employees understand the training they have received and supervise as necessary to ensure safe practices in the lab.
  - 2.4.2.2. Conduct routine lab inspections to ensure compliance with lab SOP's.
- 2.4.3. Prepare and communicate procedures for responding to accidents or injuries.
- 2.5. **Laboratory Worker/ Robot User:** The Laboratory Worker is responsible for his/her own actions in the laboratory. He/she has the following responsibilities:
  - 2.5.1. Plan and conducts each operation in accordance with Robot and Robot Systems Safety Guidelines as well as the labs SOP's.
  - 2.5.2. Immediately report any unsafe lab conditions to their Supervisor, or to EH&S.
  - 2.5.3. Informs visitors to the lab of potential hazards, safety rules or precautions.
  - 2.5.4. Attends required training sessions.
  - 2.5.5. Wears personal protective equipment as prescribed by his/her laboratory supervisor or EH&S.
  - 2.5.6. Shall ensure that safeguards are in place and functional.
  - 2.5.7. Reports to the laboratory supervisor, or EH&S any accidents/incidents that resulted in an injury or has the potential for causing an injury.
- 3. Definitions (See ANSI Standards)
- 4. Training: Robot and Robot Systems Safety will be documented and provided by the Laboratory Safety Supervisor. **Documented training must be provided prior to operating or entering the envelope of any robot or robot system.** See Appendix A - Site-Specific Robotics Safety Training Checklist for required training topics and documentation. Training will include the following topics:
  - 4.1. Location of emergency contact names and phone numbers (including Public Safety, EH&S and Lab Personnel)
  - 4.2. Location of the laboratory's Robot and Robot System Safety Guidelines.
  - 4.3. Location of written SOP for each robot system, or application.

- 4.4. Location of laboratory personal protective equipment (PPE) and policy for accessing or ordering.
  - 4.5. Hazards of the Robotic System: (The Robot, Entrapment Hazards, Impact Hazards, end effectors, energy sources, electrical hazards, etc.,)
  - 4.6. Limitations and need for redundant safety features (Software system failure, operator error; defeating interlocks, etc.,)
  - 4.7. Robot Safety: (Teach Pendant, Dead man Switch, E-Stop Buttons, Servo Disconnect, Hard Stops or Envelope limiting devices, etc.)
  - 4.8. System Safety in Use: (Awareness Devices such as warning horns and lights, Interlocks, Barriers, Light Screens, Mats, etc.,)
  - 4.9. Teaching Procedures
  - 4.10. Maintenance/Repair Procedures.
  - 4.11. Machine Guarding Requirements.
  - 4.12. Site specific Lock Out Tag Out for Robot System
  - 4.13. Laboratory policy with regard to room security (e.g. key policy), supervision and visitors
  - 4.14. Recognition of warning signs and Labels
  - 4.15. Response to spills, accidents, injuries, illnesses and/or fires (e.g. contact personnel, forms, first-aid policy)
  - 4.16. Location of nearest fire extinguisher and exits.
  - 4.17. Circumstances under which you should decide to use fire extinguisher (e.g. knowledge, experience, fire in escape path)
  - 4.18. Location of nearest safety shower and eyewash station; demonstration of how to activate/use it, and contact lens precautions
  - 4.19. EH&S OSHA training for Lock Out Tag Out.
5. **Guidelines for specific Robot and Robot System Research Applications:**
- 5.1. **Guidelines for laboratories that manufacture/remanufacture or rebuild robots:** Research involving the design of new or novel robotic equipment must follow the recommendations outlined in Clause 4 of *ANSI/RIA R15.05 – 1999*. Specific attention will be placed on engineering out any potential hazards and protecting the worker from exposure to robot components or hazards associated with the robots work process. Safety processes must be functional even if there is a loss in power, hydraulic pressure, pneumatic pressure or other energy sources involved in operating the robot. Robot design shall prevent unintended operation and prevent any hazards due to any reasonably foreseeable failure of the robot or robot system. All manufactured/remanufactured or rebuilt robots must provide updated “Required Information” as detailed in 4.16 of ANSI/RIA R15.05 – 1999 so that all end users are aware of any changes in performance and safe operation of the robot/equipment.
  - 5.2. **Guidelines for laboratories that manufacture or design robot safety devices:** Research involving the design of new or novel robotic equipment must follow the recommendations outlined in Clause 5 of *ANSI/RIA R15.05 – 1999*. Clause 5 provided detail on the design requirements of barrier guards, interlocks, stop signals,

safety light curtains/screens, area scanning devices, radio frequency/capacitance safeguarding devices, safety mat systems, beam safety systems and two hand control systems.

- 5.3. **Guidelines for the installation of robots and robot systems:** All robot systems must be installed according to the recommendations outlined in Clause 6 of *ANSI/RIA R15.05 – 1999*. Safeguarding must be installed according to Clause 7 of *ANSI/RIA R15.05 – 1999*. Installers must ensure that the laboratory/works space has the proper ventilation (snorkel exhaust, fume hood, etc.) and environmental conditions are safe for the work to be performed. Limiting devices must be tested at maximum load and extension to confirm that the robot will stay within the designed safety envelope (minimum 18 inches from any structure to prevent trapping or pinch points) , protect lab occupants and to protect building structures.
6. **Hazards:** Laboratory's operating Robotic devices must conduct a thorough hazard investigation of their process and develop standard operating procedures for controlling the hazards associated with their robotic device or robotic system. A hazard assessment must be conducted every time a new robot, process or auxiliary device has been changed. The following are hazards associated with robot and robot systems
  - 6.1. **Moving Mechanical Equipment:** Trapping or Crushing hazards
  - 6.2. **Auxiliary devices operated by the robots:** welding guns, saws, painting, gripping tools, etc.
  - 6.3. **Power Sources and Stored Energy:** Electrical, hydraulic or pneumatic.
  - 6.4. **Hazardous Materials Used:** Flammables, Corrosives, Toxic, etc.,
  - 6.5. **Noise**
  - 6.6. **Interference:** Electrical, Radio, Magnetic or Vibrational.
  - 6.7. **Ergonomics**
  - 6.8. **Human Error**
  - 6.9. **Safety Device failure**
7. **Safeguarding Personnel:** In order to properly protect workers operating near robot systems, safeguards need to be designed and implemented so that the lab occupant cannot enter a safeguarded space without implementing appropriate entry procedures. Safeguarding personnel can be achieved by two processes.
  - 7.1. **Prescribed Method:** Utilizing the prescribed method discussed in Clause 8 of *ANSI/RIA R15.05 – 1999*.
  - 7.2. **Risk Assessment Method:** Utilizing the prescribed method discussed in Clause 9 of *ANSI/RIA R15.05 – 1999*.

Unless a proper Risk Assessment has been conducted, safeguarding will be implemented according to the *Prescribed Method*. The supervisor of the robot or robot system choosing to apply the *Risk Assessment Method* will be responsible for conducting the risk assessment in the design phase and adjusting the risk assessment through to project completion. Any changes to the process/system will require a revised risk assessment. **The most current risk assessment must be kept on file.**

- 7.3. **Safeguards for personnel consist of , but are not limited to the following devices:**

### **7.3.1. Personnel Protection Outside restricted space:**

7.3.1.1. **Interlock Barriers and/or Presence Sensing Devices:** These are designed for general personnel protection: Besides lab personnel, controlled access for ancillary (plumbers, electricians, police, EH&S, custodians, etc..) staff should also be considered.

7.3.1.1.1. **Barriers and guarding** must be designed so that it is impossible to enter restricted space while robotic systems are operational, but will permit planned entry when safeguards for planned entry have been implemented.

7.3.1.1.2. **Presence Sensing Devices** Include

7.3.1.1.2.1. Pressure-Sensitive Devices: Mats, plates, or pressure sensitive strips placed near the restricted space.

7.3.1.1.2.2. Presence Sensors: Photoelectric eye or a light curtain using light emitting diodes.

7.3.1.2. Software Programs

**7.3.2. Personnel protection within the restricted space (envelope):** Hazardous devices will be deactivated or safeguarded. Procedures for entry will include:

7.3.2.1. The implementation of minimum clearance distances from the restricted space for high speed attended program verification (APV).

7.3.2.2. Limiting speed for slow speeds control as required in clause 4.9 of *ANSI/RIA R15.05 – 1999* or for “Program Verification” use the safeguarding described in clause 10.8 of *ANSI/RIA R15.05 – 1999*.

7.3.2.3. Adherence to teaching procedures

7.3.2.4. Adherence to safeguarding requirements for maintenance activities.

7.3.2.5. Emergency Devices

7.3.2.5.1. Emergency stop buttons

7.3.2.5.2. Enabling devices

**8. Maintenance and Repair:** Safe Operation of the robots requires that a maintenance plane be implemented. Maintenance and Repair of the robot system will often require entry into the restricted space and must be included in the laboratory’s SOP’s.

### **9. Record Keeping:**

9.1. Signed Site Specific Training Records for each Robotics Lab employee.

9.2. Updated “Required Information” Sheets for manufactured, remanufactured or rebuilt robot/equipment

9.3. Current Risk Assessment (If the Risk Assessment method is chosen)

9.4. Current Copy of the *American National Standard of Industrial Robots and Robot Systems – Safety Requirements* (Currently *ANSI/RIA R15.05 – 1999*)

9.5. Current Copy of any supplements to *ANSI/RIA R15.05* that may be utilized in developing the safety program.

9.6. Current Copy of the *Oakland University Robot and Robot Systems Safety Guidelines*



**10. Injuries:** All injuries need to be reported to your supervisor and EH&S. Life threatening injuries should be immediately reported to the University Police by dialing 911 on a campus phone or by dialing 248-370-3331 on a cell phone. Non-Life threatening injuries should be evaluated by the Graham Health Center Clinic (Phone: 248-370-2341), and after hours injuries should be evaluated by the emergency room at Crittenden Hospital.

**11. Appendix**

11.1. Appendix A - Site Specific Training Checklist

**12. Glossary:**

**13. References:** American National Standard for Industrial Robots and Robot Systems - Safety Requirements (ANSI/RIA R15.06-1999).

## Chapter 8: Review of Biohazardous Agents and Recombinant DNA

Oakland University (OU) is committed to the highest standards of safe and ethical Biosafety research compliance in Biosafety. For this purpose, OU has instituted an Institutional Biosafety Committee (IBC) to provide local review and oversight of nearly all forms of research utilizing recombinant DNA and/or biohazardous materials. The IBC has the responsibility of reviewing a variety of experimentation that involves biological materials (e.g., infectious agents) and other potentially hazardous agents (e.g., carcinogens). All research, teaching and testing at OU involving recombinant DNA, infectious agents, select agents and/or cultured cell lines must be approved by the IBC before research begins.

### 8.1 Application Process

IBC approval is obtained through submission of a research application using the Grants, Contracts and Sponsored Research electronic research management system. <https://www2.oakland.edu/research/gcsram/login.cfm> The committee will review the application and will approve, approve with conditions, or deny approval of the proposed activity. In some cases, the committee may exempt projects from further committee review. Depending on the biosafety level of the experiments, approval is granted for a maximum of five years. Application annual reviews and laboratory audits are performed by the BioSafety Officer (BSO) and reported to the IBC. All applicants are held responsible for taking the steps necessary to ensure that all work is conducted as specified in the application and meets the requirements set forth in the federal, state and local laws and regulations.

### 8.2 The Institutional Bio-safety Committee (IBC)

The IBC is composed of at least five members. The committee includes two community representatives who are not affiliated with OU, and the BSO. The committee meets at least quarterly, but will meet as needed commensurate with the volume of protocols needing review, the nature and risks of the research, and the need for continuing oversight.

Requirements for committee membership include:

- Experience and expertise in Recombinant DNA technology and Biosafety and Physical containment
- Knowledge of Institutional commitments and policies, applicable laws, standards of professional conduct and practice, community attitudes and the environment.
- The capability to assess the safety of recombinant DNA and Biological Agents research and identify potential risks to public health and safety

The IBC is charged with the review of recombinant DNA research projects for compliance with the National Institute of Health (NIH) Guidelines.

[http://oba.od.nih.gov/rdna/nih\\_guidelines\\_oba.html](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html)

The review may include:

- A. Containment levels; some useful resources to refer to when assessing containment levels are:
  - a. Table 1: Basis for the Classification of Biohazardous Agents by Risk Group (RG) [http://oba.od.nih.gov/oba/rac/guidelines\\_02/APPENDIX\\_B.htm](http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_B.htm)
  - b. Physical Containment [http://oba.od.nih.gov/oba/rac/guidelines\\_02/APPENDIX\\_G.htm](http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_G.htm)

- c. Biological Containment  
[http://oba.od.nih.gov/oba/rac/guidelines\\_02/APPENDIX\\_I.htm](http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_I.htm)
  - d. Physical Containment for Large Scale Uses of Organisms Containing Recombinant DNA Molecules  
[http://oba.od.nih.gov/oba/rac/guidelines\\_02/APPENDIX\\_K.htm](http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_K.htm)
  - e. Physical and Biological Containment for Recombinant DNA Research Involving Plants  
[http://oba.od.nih.gov/oba/rac/guidelines\\_02/APPENDIX\\_P.htm](http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_P.htm)
  - f. Physical and Biological Containment for Recombinant DNA Research Involving Animals  
[http://oba.od.nih.gov/oba/rac/guidelines\\_02/APPENDIX\\_Q.htm](http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_Q.htm)
- B. Facilities
  - C. Institutional procedures and practices, and
  - D. Training and expertise of personnel
  - E. Notifying the principal investigator of IBC review and approval
  - F. Setting containment levels and modifying containment levels for ongoing experiments as warranted
  - G. Implementing contingency plans for handling accidental spills and personnel contamination resulting from recombinant DNA research; and
  - H. Report to OBA and institutional officials within 30 days any:
    - a. Substantial problems or violations of the NIH Guidelines; and
    - b. Significant research related accidents or illnesses.

For human gene transfer experiments, the IBC is responsible for ensuring that:

- A. All aspects of Appendix M of the NIH Guidelines have been addressed by the principal investigator  
[http://oba.od.nih.gov/oba/rac/guidelines\\_02/APPENDIX\\_M.htm](http://oba.od.nih.gov/oba/rac/guidelines_02/APPENDIX_M.htm)
- B. Final IBC approval is granted after the RAC review process is complete; and
- C. Research projects are in compliance with the institution's health surveillance requirements and data and adverse event reporting requirements.

All researchers conducting research involving biohazardous materials need to be familiar with the Biosafety in Microbiological and Biomedical Laboratories (BMBL) Manual. <http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm> Investigators are responsible for conducting the research as described in the approved or exempted application and for submitting a revision to the application describing any departures from the original before revisions are implemented. Researchers should know that research might be subject to intramural inspection or audit.

Through its program, the OU IBC ensures that all research, teaching, and testing involving recombinant DNA, infectious agents and cultured cell lines comply with all relevant government rules and regulations. Information about the biosafety program is available at the university's research web site. <http://www4.oakland.edu/?id=6069&sid=201>

### **8.3 Training**

All OU laboratory workers are required to receive safety, health, and environmental information and training prior to working in the laboratory. The training that is required for a particular laboratory worker is based in part on the potential exposures in the work place and as required by state and federal regulatory agencies.

The following are guidelines to assist you in determining the training courses that you should attend. Discuss the guidelines with your supervisor and determine the appropriate training that will be required. Once the appropriate training has been determined, you must contact EH&S at ext. 4196 to schedule your training.

Please visit **Laboratory Safety & Compliance** at <http://www4.oakland.edu/?id=6069&sid=201> for details or contact Lab Safety personnel at (248) 370-4196.

OU offers the following training courses in Laboratory Safety:

- 1) General Laboratory Safety (Right to Know)
- 2) Biosafety
- 3) Bloodborne Pathogen Exposure Control
- 4) Laser Safety
- 5) Radiation Safety
- 6) Radiation Awareness
- 7) Analytical X-Ray and Radiation Producing Machines Safety
- 8) Robotics Safety
- 9) Hazardous Materials and Waste Management
- 10) Shipment of Biological and Hazardous Materials
- 11) Laboratory LockOut/Tag Out

For question regarding laboratory biosafety matters or for Biosafety Training, contact the Laboratory Compliance Manager, at 248-370-4314 or visit the Laboratory Safety and compliance web page. <http://www4.oakland.edu/?id=6092&sid=20>

#### **8.4 Biosafety Guidelines**

*Federal regulations require oversight on the use of Recombinant DNA and Biohazardous Materials in research. The regulations may be accessed at the links below.*

- a. **NIH Guidelines for Research Involving Recombinant DNA Molecules**  
[http://oba.od.nih.gov/oba/rac/guidelines\\_02/NIH\\_Guidelines\\_Apr\\_02.htm](http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm)
- b. **Biosafety in Microbiology and Biomedical Laboratories (BMBL)**  
<http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm>

#### **8.5 IBC Application and Forms**

For access to the application to have your research reviewed by the Institutional Biosafety Committee please see below.

- a. **GCSR electronic research management system**  
<https://www2.oakland.edu/research/gcsram/login.cfm>
- b. **User Instruction Sheet**  
[http://www2.oakland.edu/research/research\\_new/pages/pages.cfm?page\\_id=27](http://www2.oakland.edu/research/research_new/pages/pages.cfm?page_id=27)
- c. **IBC Application Questions**  
<http://www4.oakland.edu/?id=6069&sid=201>

- d. **Continuing Review/Completion Form**  
[http://www2.oakland.edu/research/research\\_new/pages/pages.cfm?page\\_id=27](http://www2.oakland.edu/research/research_new/pages/pages.cfm?page_id=27)

## 8.6 University Biosafety Services

OU's Biosafety Program is designed to prevent employee injuries from exposures to hazardous biological agents. The following links provide access to the university's Biosafety Program as well as online guidance on the safe handling of biological agents from various government and professional organizations. Please contact the Biosafety Officer at (248) 370-4196 for any questions regarding biosafety.

Please visit **Laboratory Safety & Compliance** <http://www4.oakland.edu/?id=6069&sid=201> for details regarding the Biosafety services listed below

### a. **Biohazardous and Medical Waste**

#### **Frequently Asked Questions**

- 1) How do I dispose of contaminated sharps?  
Contaminated sharps are managed as follows:
  - Broken glassware which may be contaminated is picked up using mechanical means, such as a brush and dust pan.
  - All contaminated sharps are discarded immediately or as soon as possible into a sharps safe.
  
- 2) How do I launder my lab coat?  
Contaminated laundry is managed as follows:
  - Send out to those laundry facilities in the area willing and able to handle biohazardous laundry. The **Graham Health Center** can provide the name(s) of current facilities that perform this function.
  - Place in leak-proof, labeled or color-coded containers before transport
  - Handle as little as possible by OU employees, and never take contaminated materials home for laundering.
  
- 3) What are the guidelines for the use of biohazard bags, hampers and sharps safes containing biohazardous waste?
  - Maintained upright at all times
  - Replaced routinely and not overfilled
  - Secure and seal the container prior to removal to prevent spillage or protrusion of contents during handling
  
- 4) How do I dispose of my biohazardous waste containers?
  - Transport your biohazardous containers to the Office of EH&S
  - An "OU Medical Waste Internal Tracking Form" (**MedWasteForm.pdf**) shall be completed for each "drop-off" (regardless of the number of containers), and brought (with the waste) to the Office of Environmental Health and Safety, in the Graham Health Center.
  - An individual from the Office of Environmental Health and Safety will review the manifest, keep two copies, and issue the bearer a key to the Phoenix Cage (located in the basement of the Graham Health Center).

- At the time of drop-off, departments may also pick up empty biohazard hampers and/or sharp safes from the Phoenix Cage as needed. The biohazard hampers are available at no charge; however departments must provide EH&S with an IDC slip in order to purchase sharp safes.
- Once every two weeks, our medical waste vendor shall remove the hampers/sharp safes from the Phoenix Cage, and transport them first to a Treatment Center for high-temperature decontamination, and disposal.

Please visit **Laboratory Safety & Compliance** web page for details or contact Lab Safety personnel at (248) 370-4196.

#### **b. Shipping of Hazardous Materials**

Federal rules require that anyone wishing to ship biological material, hazardous material, and/or dry ice must first receive shipping training. Hazardous material is defined as any material or substance that poses a risk to the health and safety of the public, property or the environment during transportation. Examples of commonly shipped material that may be regulated are: alcohols, such as ethanol solutions, formaldehyde solutions, xylene, chemical mixtures, newly synthesized compounds, solvents, lubricants, and corrosives (acids or bases which are corrosive to the skin). Regulations may also apply to some commercial products such as paints, batteries, cleaning products, etc.

DOT specifically defines the hazardous substance as any material that is listed in the 49 CFR Hazardous Materials Table which can be accessed at: **CFR 49 Hazardous Materials**.

If you anticipate a need to ship any of these types of materials you must first submit an Intent to Ship Biological or Hazardous Material Form.

Please visit **Laboratory Safety & Compliance** web page for details or contact Lab Safety personnel at (248) 370-4196.

## Chapter 9: Human Subjects in Research

### 9.1 Safe and Ethical Human Subject Research at OU

Oakland University (OU) is committed to the highest ethical standards of human participant research as required by local, state, and federal laws and regulations and the ethical principles set down in the Belmont Report <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>, the Declaration of Helsinki <http://www1.va.gov/oro/apps/compendium/Files/helsinki89.htm> and the Nuremberg Code <http://www.hhs.gov/ohrp/references/nurcode.htm>. The Office of Grants, Contracts and Sponsored Research is committed to creating an institutional culture that values integrity in the conduct of research as well as the pursuit of knowledge and innovation that provide human benefit.

**All research involving the participation of human participants or their private records, regardless of funding, must be submitted for review by the Institutional Review Board (IRB) before research may begin.**

An application may be submitted electronically by using the GCSR electronic research management system, which can be accessed at the Human Subject Research webpage. <http://www2.oakland.edu/research/appmanager/>

The IRB will only review applications for research conducted by OU faculty, staff or students, or others who are formally sponsored by OU faculty.

### 9.2 Authority

OU has established a Federal wide Assurance through the Office of Human Research Protection (OHRP) to conduct human participant research. OU's FWA covers all human participant research, both biomedical and behavioral, conducted at OU regardless of the source of funding. OU's FWA covers faculty, employees of OU and its students, trainees and anyone conducting such research under the auspices of OU.

### 9.3 Definition of Human Subject Research

Research must meet the Department of Health and Human Subjects or the Food and Drug Administration definition of "research" and "human" to be considered Human Subject Research. Human Subject Research is defined by the Department of Health and Human Services (DHHS) and the Food and Drug Administration as:

#### a. Research

Under **DHHS** regulations, "research" means a systematic investigation, including development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Under **FDA** regulations research means any experiment that involves:

- 1) **a test article** and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Food, Drugs, and Cosmetics Act, or need not meet the requirements for prior submission to the FDA under these sections of the Food, Drug, and Cosmetics Act, but the results of which

are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

- 2) **drugs**, an experiment is any use of a drug, except for the use of a marketed drug in the course of medical practice, and is defined as a systematic investigation designed to develop or contribute to generalizable knowledge.

**b. Human Participant (subject)**

The **DHHS** defines “human subject” as a living individual about whom an investigator (whether professional or student) conducting research obtains:

- 1) Data through intervention or interaction with the individual.

Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

- 2) Identifiable private information

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

The **FDA** definition of human subject is an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be either a healthy individual or a patient. For research involving medical devices a human subject is also an individual on whose specimen an investigational device is used.

**9.4 Institutional Review Board**

The OU Institutional Review Board (IRB) is composed of at least five members of varying backgrounds with the necessary scientific expertise or knowledge of the community necessary to promote the rights and welfare of human participants, at least one member must be a person whose primary concerns are in non-scientific areas and a member who is not affiliated with the University. Members may not vote on or participate in review of research in which they or their family have a conflict of interest except to provide information requested by the IRB.

The IRB has the authority and responsibility to approve, require modifications to, or disapprove all human subject research, before it is initiated, in order to comply with ethical principles and federal, state and local regulations and institutional policy. The IRB provides continuing oversight of all human participant research, all but exempt research protocols are reviewed at



least yearly. The IRB has the authority to assure on an ongoing basis, that the risks of proposed research are justified by the potential benefits to the participants and to society, that the risks do not fall disproportionately on one group and that risks are minimized to the extent possible consistent with sound research design. The IRB are authorized to oversee the consenting process to ensure that agreement by an individual to participate in research is voluntary and knowing. Individuals who are particularly vulnerable (pregnant women, fetuses, children, prisoners, students, employees, or those whose capacity to consent may be in doubt) require additional protection during the consent process.

To prevent undue influence, the IRB acts independently of University officials or anyone who is not an official member of the committee. No individual shall attempt to influence the IRB inappropriately on any matter before the IRB, or within the IRB's jurisdiction. The Vice Provost for Research has the authority to oversee compliance issues and is charged with investigating allegations of undue influence upon the IRB and with taking corrective action if necessary.

When reviewing a proposal, the board considers:

- 1) the risks to subjects
- 2) the anticipated benefits
- 3) the importance of the knowledge that may result
- 4) the informed consent process to be employed

The board is particularly stringent when considering applications for research involving fetuses, pregnant women, prisoners, children, the cognitively impaired or other potentially vulnerable groups.

Investigators are responsible for conducting the research as described in the approved or exempted application and for submitting a revision to the application describing any departures from the original before revisions are implemented. Researchers must not collect data while the modified application is being reviewed. Data collected during this time cannot be used. Researchers should know that research might be subject to intramural inspection or audit.

### **Types of IRB Review**

There are several types of IRB reviews based on the type of research being conducted and the risk level. Ultimately the IRB will decide the type of review a protocol will require.

#### **a. Exempt Review**

Protocols that the IRB has determined do not meet the definition of human participant research and therefore, the federal regulations do not apply. Once determined to be exempt the research will not be reviewed by the full IRB committee, or its designee, again unless there are changes to the study. If changes do occur, the protocol must be re-submitted to the IRB for review to determine if the changes involve an increased risk to the participants. No data may be collected until the IRB determines that the modified research has been approved. Any data collected when human participant research has not been approved cannot be used. Research must fall into one of the following six categories to be determined exempt.

- 1) Research conducted in established or commonly accepted educational settings, involving normal educational practices such as:
  - research on regular and special education instructional strategies, or
  - research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- 2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- 3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 2 above, if:
  - the human subjects are elected or appointed public officials or candidates for public office; or
  - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. **(Note: To qualify for this exemption the data, documents, records, or specimens must be in existence before the project begins.)**
- 5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
  - public benefit or service programs, or
  - procedures for obtaining benefits or services under those programs, or
  - possible changes in or alternatives to those programs or procedures,
  - possible changes in methods or levels of payment for benefits or services under those programs.
- 6) **Taste and food quality evaluation and consumer acceptance studies if:**
  - wholesome foods without additives are consumed, or
  - food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

#### Research That Does Not Qualify for Exemption

- 1) Research projects cannot be exempted from review if:
  - information is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects or
  - any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- 2) An investigator cannot exempt his or her own research project from review by the IRB. He or she must receive "concurrence" from a designated member of the IRB.
- 3) If an investigator changes the research project in a way that affects
  - how human subjects are enrolled,
  - the collection of additional identifiers connected to an individual enrolled in the project, or
  - the data collected on individuals after obtaining "concurrence" by a designated member of the Human Investigation Committee, the investigator must notify a designated member of the IRB for "concurrence" that the project continues to be eligible for exemption from IRB review.
- 4) All projects involving Genetics will be referred to the full board IRB for review and approval.
- 5) If an investigator does not agree with the opinion of the designated member of the IRB, the investigator may appeal to the IRB.
- 6) The designated member of the Human Investigation Committee cannot "concur" that a research project is eligible for "Exemption" after the project has been initiated.
- 7) A designated member of the IRB that is assigned the responsibility for "concurring" that a research project is exempted from HIC review cannot "concur" on a project in which he/she is a participant

**b. Expedited Review**

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. The IRB will be informed of all expedited approvals at the next meeting. Research that meets the following categories may be reviewed by an expedited procedure.

Research activities that:

- present no more than minimal risk to human subjects, and
- involve only procedures listed in one or more of the expedited categories below. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Expedited Research Categories**

- 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

- a) Research on drugs for which an investigational new drug is not required.
  - b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 2) Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:
- From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
  - From other adults and children<sup>2</sup>, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- 3) Prospective collection of biological specimens for research purposes by non-invasive means. Examples are:
- hair and nail clippings in nondisfiguring manner
  - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
  - permanent teeth if routine patient care indicates a need for extraction
  - excreta and internal secretions (including sweat)
  - uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
  - placenta removed at delivery
  - amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
  - supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
  - mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
  - sputum collected after saline mist nebulization.
- 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
- physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
  - weighing or testing sensory acuity;
  - magnetic resonance imaging;
  - electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;

- moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- 5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subject. 45 CFR 46-101(b)(4). This listing refers only to research that is not exempt).
  - 6) Collection of data from voice, video, digital, or image recordings made for research purposes.
  - 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, or quality assurance methodologies.
  - 8) Continuing review of research previously approved by the convened IRB as follows:
    - where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    - where no subjects have been enrolled and no additional risks have been identified;
    - or where the remaining research activities are limited to data analysis.
  - 9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**c. Full Board Review**

All human subject research that does not meet the requirements for exempt or expedited review will be determined by the full committee at the next available meeting. The research may be approved, modifications may be requested or the research may be disapproved. The determination will be made by a majority vote of a quorum of the committee members. A scientist, non-scientist and community member must be present to meet the requirements for a quorum.

Full Board Review is required for:

- Initial applications that are not eligible for exempt or expedited review procedures.
- Revisions that are non-minor changes.
- Renewals of projects that initially required full board; and
- Disapproval of a project, regardless of review level.
- Issues in which resolution cannot be made between the IRB reviewer and the investigator.

The expedited review procedure may not be used where:

- identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be HIC stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than normal.
- The expedited review procedure may not be used for classified research involving human subjects.
- The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.
- Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

## **9.5 Education and Training**

OU's Office of Grants, Contracts and Sponsored Research assumes the responsibility for providing education to the research community on ethical principles, laws, policies, regulations and University policy concerning human participant research. To facilitate this responsibility the Regulatory Compliance Coordinator and Research Compliance Manager will hold training seminars for research administrators, research investigators, key personnel and appropriate staff.

Research may not begin until the Principal Investigator and all key personnel have completed online training. Any data collected without the approval of the Institutional Review Board may not be used. To access the CITI training link please see below.

[http://www2.oakland.edu/research/research\\_new/pages/pages.cfm?page\\_id=26](http://www2.oakland.edu/research/research_new/pages/pages.cfm?page_id=26)

## **9.6 IRB Application and Forms**

The application to conduct human participant research and other relevant forms are listed below. This is a partial list. To find the complete list and the most up to date version, view our website at ([http://www2.oakland.edu/research/research\\_new/pages/pages.cfm?page\\_id=26](http://www2.oakland.edu/research/research_new/pages/pages.cfm?page_id=26))

- The Application: Grants, Contracts and Sponsored Research electron research management system <http://www2.oakland.edu/research/appmanager/>
- IRB Application Questions ([http://www2.oakland.edu/research/research\\_new/pages/pages.cfm?page\\_id=26](http://www2.oakland.edu/research/research_new/pages/pages.cfm?page_id=26))
- Consent Form Checklist ([http://www2.oakland.edu/research/research\\_new/pages/pages.cfm?page\\_id=26](http://www2.oakland.edu/research/research_new/pages/pages.cfm?page_id=26))
- Continuing Review/Completion Form ([http://www2.oakland.edu/research/research\\_new/pages/pages.cfm?page\\_id=26](http://www2.oakland.edu/research/research_new/pages/pages.cfm?page_id=26))

## 9.7 Policies, Guidelines, Regulations and Ethical Principles

OU complies with the Code of Federal Regulations (CFR), the Common Rule, as it applies to human participant research. These include the regulations from DHHS [45 CFR 46] and its subparts, the FDA regulations [21 CFR 50 and 56], and all other relevant federal regulations.

Through its program, the IRB ensures that all research associated with OU complies with all relevant government rules and regulations. The OU *Guidelines for Research Involving Human Subjects* and federal guidelines are available at the University's research website. [http://www2.oakland.edu/research/research\\_new/pages/pages.cfm?page\\_id=26](http://www2.oakland.edu/research/research_new/pages/pages.cfm?page_id=26)

- a. Human Subject Research is based on the following ethical principles.
  - Belmont Report <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
  - Nuremberg Code <http://www.hhs.gov/ohrp/references/nurcode.htm>
  - Declaration of Helsinki <http://www1.va.gov/oro/apps/compendium/Files/helsinki89.htm>
- b. Federal Regulations
  - Office of Human Research Protection <http://www.hhs.gov/ohrp/>
  - Food and Drug Administration <http://www.fda.gov/CDER/GUIDANCE/>
- c. OU Guidelines for Research Involving Human Subjects  
[http://www2.oakland.edu/research/research\\_new/pages/files/File/IRB\\_Guidelines.pdf](http://www2.oakland.edu/research/research_new/pages/files/File/IRB_Guidelines.pdf)

## 9.8 Contacts

For questions regarding application submissions or training contact the Regulatory Compliance Coordinator, at 248-370-4898

For questions regarding IRB Guidelines or Federal Regulations contact the Research Compliance Manager at 248-370-4924

For questions or complaints regarding the IRB or compliance staff, please contact the Research Compliance Manager at 248-370-4924

For questions concerning possible influence on the IRB please contact the Vice Provost for Research at 248-370-2552.

For more information and links to documents and guidelines, please visit the Human Subject webpage under Regulatory Compliance in the Research Office website [http://www2.oakland.edu/research/research\\_new/pages/](http://www2.oakland.edu/research/research_new/pages/)

## Chapter 10: Laboratory Animals in Research

### 10.1 Institutional Animal Care and Use Committee By-Laws and Animal Welfare Assurance

Oakland University (OU) is committed to the highest standards of research compliance regarding the humane treatment of animals in research. At OU, researchers and faculty sponsors assure the humane use and care of animals in activities they conduct or which are conducted under their direction. They have a direct responsibility to see that animals are adequately cared for and properly used.

Before investigators or faculty sponsors can procure animals or initiate any research, testing, or instructional project involving the use of vertebrate animals, they must submit an application to and receive approval from the Institutional Animal Care and Use Committee (IACUC). <https://www2.oakland.edu/research/gcsram/login.cfm>

**No research on animals may be conducted without approval by the OU Institutional Animal Care and Use Committee (IACUC). Any data collected without approval of the IACUC cannot be used.**

The purpose of the IACUC is to oversee and evaluate the University's Animal Care and Use Program to assure the responsible and humane care and use of animals used in approved research and education protocols. The Vice Provost for Research (VPR) is the Institutional Official for OU's Animal Care and Use Program. The VPR is authorized to legally certify on behalf of the University that requirements of the Animal Welfare Act (AWA; 7 USC, 2131) and the University's Public Health Service (PHS) OLAW Animal Assurance Statement are being met.

#### a. Institutional Animal Care and Use Committee (IACUC)

OU has established an Institutional Animal Care and Use Committee, which is qualified through the experience of its members, to oversee the University's Animal Care and Use Program, its facilities, and procedures. The IACUC consists of at least five members, and its membership meets the compositional requirements set forth in the PHS Policy at IV.a.3.b. IACUC members are appointed by the University President, on the recommendation of the Vice Provost for Research. Committee appointments are for a term of three years and are renewable.

The committee fulfills its purpose by monitoring compliance with all State and Federal rules and regulations, fulfilling requirements of granting agencies, and following the *Guide for the Care and Use of Laboratory Animals* established by the National Research Council. The Program of Animal Care and Use also operates according to the PHS Policy on the Humane Care and Use of Laboratory Animals.

The purpose of the IACUC is to:

- 1) Operate as the policy making body and oversee the University's Animal Care and Use Program, its facilities and training program, and report directly to the Institutional Official.
- 2) Meet monthly (or more frequently if required) and maintain minutes of its meetings.



- 3) Review the Animal Care and Use Program and inspect all animal facilities at least once every six months using the Guide for the Care and Use of Laboratory Animals (Guide), the USDA Animal Welfare Act, Title 9, chapter 1, subchapter A, the IACUC's Checklist for Review of Program and Facilities, and the previous IACUC semiannual report as resources for their evaluations. A subcommittee of the IACUC consisting minimally of the Chair, University Veterinarian, and the Animal Research Facility Manager, is required for these reviews. All IACUC members have the opportunity and are encouraged to participate.
- 4) Prepare a report for each semi-annual review and inspection, which describes the nature and extent of the University's adherence to the Guide, the Animal Welfare Act, and the PHS policy as set forth in IV, B, 3, including specific plans to address any deficiency, and submit the report to the Institutional Official. Semiannual reports of the IACUC evaluations are maintained and made available to the Office of Laboratory Animal Welfare (OLAW).
- 5) Review and address any concerns involving the care and use of animals at the university to the appropriate administrator(s) and investigator(s).
- 6) Review and address concerns by developing recommendations and forwarding them to the Institutional Official with copies of the recommendations to the appropriate investigator(s).
- 7) Make written recommendations to the Vice Provost for Research regarding any aspect of the University's animal program facilities, or personnel training.
- 8) Review and approve, require modifications in (to secure approval), or withhold approval of all animal use proposals.
- 9) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes in protocols involving animals in on-going projects.
- 10) Notify investigators in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval.
- 11) Conduct continuing review of each previously approved, ongoing activity at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV. C. 1-4 at least once every three years.
- 12) Suspend an activity involving animals in accordance with the specifications set forth in IV.C.6 of the PHS Policy

**b. Animal Care and Use Protocol Review and Approval**

An investigator must submit the IACUC's, Application for Use of Vertebrate Animals (AUVA) electronically through the University's Research Application Manager (RAM) system at, <https://www2.oakland.edu/research/gcsram/login.cfm>.

Once entered into the system, IACUC members receive an email informing them that an IACUC application has been added to their work list and request the member to log into the system to review the application. If the application proposal involves the potential for animals to experience levels of pain, discomfort, or distress that cannot be classified as those for which pain-relieving drugs would not be customarily given in human medicine or standard veterinary medicine (USDA Category C), the applicant is required to consult the University Veterinarian prior to submitting their application. During this consultation, the veterinarian makes recommendations to alleviate associated pain or potential distress and advises the PI on the appropriate analgesic and anesthetic agents to be used that are specific to species and procedures proposed.

New applications or submissions requesting significant changes of a currently approved application are requested to be submitted a minimum of ten days prior to the next scheduled IACUC meeting. Although all IACUC members have access to the RAM system, hardcopies of all meeting materials are also mailed to the committee's non-affiliated/community member and University Veterinarian to assist them with their review. All items requiring action from the IACUC are dealt with and discussed at full committee meetings. Principal Investigators are encouraged to be available to attend the meeting, or to be contacted by phone, to discuss their proposed studies and field any associated questions that the IACUC may have. If they are in attendance at the meeting, they are dismissed from the meeting prior to any continued committee discussion and voting.

All projects have a maximum approval period of up to three years. All Principal Investigators who have projects that have an approval period greater than one year are required to submit a properly completed Annual Review Form two months prior to the yearly anniversary date of the IACUC's original approval of the project. At the completion of the project the Principal Investigator is required to submit the IACUC's Project Completion Form. If a proposal application requires more than three years conducting, a new AUVA form is required to be submitted and approved by the IACUC two months prior to the end of the initial three year approval period.

**c. Approval Status Options**

- 1) Full Approval – Investigator may proceed with initiation of the project.
- 2) Requires Modifications – Modifications are required to secure IACUC approval. Investigator must respond satisfactorily to committee requests for changes and/or clarifications by modifying their submitted application accordingly. The revised application is reviewed by a designated review subcommittee, appointed by the IACUC Chairperson and the University Veterinarian, to confirm satisfactory response to any issues identified during the committee's initial review and may then receive Full Approval. The full committee then reviews the response and is asked to endorse the subcommittee's approval at the next IACUC meeting.
- 3) Tabled – Investigator is required to supply additional information and/or major revisions.
- 4) Denied Approval – Major deficiencies exist, and a new application is requested.
- 5) Request for Revision – Requests for revisions to previously approved projects are handled in one of two ways. If the request is for an administrative/non-significant revision such as; addition or removal of project personnel (except for the PI or

Responsible Faculty Member), change in the source of animals, (when the source is an approved commercial vendor), or change in project dates, so long as the total project period does not exceed three years, the IACUC Chair may approve of the request on the committee's behalf after consultation with the Animal Research Facility Manager. All revision requests in this category are discussed with the full committee at their next meeting.

Requests for significant changes such as changes to: study objectives, procedures performed on live animals, number of animals, pain category, strain or species of animal, or PI and/or Responsible Faculty Member must be submitted to the full committee and reviewed and approved by the same process that is required for new applications. The IACUC's Policies and Procedures Document on Revision of Approved Protocols is available electronically. Please see below.

[http://www2.oakland.edu/research/research\\_new/pages/pages.cfm?page\\_id=29](http://www2.oakland.edu/research/research_new/pages/pages.cfm?page_id=29)

#### **d. Animal Welfare Assurance of Compliance**

Regulatory agencies and OU require that the IACUC review all research or educational projects to be conducted using live animals to assure their humane treatment. This review is required for compliance with the standards, guidelines, and policies set forth by the United States Department of Agriculture (USDA), Animal Welfare Act (AWA), Public Health Service (PHS), United States Government Principles (USGP), 9 Codes of Federal Regulation (9 CFR), the *Guide for the Care and Use of Laboratory Animals*, National Institute of Health (NIH), and the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

#### **e. Regulatory Issues and Animal Research**

Institutional animal care and use programs must comply with the regulations of several federal, state, and independent agencies. Several of the agencies and their regulatory functions that apply to laboratory animal care and use programs are:

- 1) **Interagency Research Animal Committee (IRAC)** The IRAC was convened in 1983 to discuss the U.S. Government's overall policy on the use of animals in research. The resulting "Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training", which summarizes the conservation, use, care, and welfare of research animals, has been subsequently used by all major regulatory bodies in developing specific guidelines.
- 2) **United States Department of Agriculture (USDA)** The Animal Welfare Act was first enacted in 1966 and was amended in 1971, 1976 and 1985. This act of Congress regulates the transportation, purchase, care, and treatment of animals used in research, for exhibition, and sold as pets. The Act specifically includes dogs, cats, nonhuman primates, guinea pigs, hamsters, rabbits, and wild animal species intended for use in research. The Act excludes farm animals used for agriculture research and laboratory-bred rats (*Rattus spp.*) and mice (*Mus spp.*). Note, however, these species are covered by the Public Health Service Policy.

The Animal Welfare Branch of the USDA administers the Animal Welfare Act by establishing animal care standards for most laboratory animal species known as the Animal Care Regulations. Compliance requirements include submission of an annual

report totaling the number of animals receiving anesthetics, analgesics, and sedatives for potential pain and distress and the number of animals used under conditions of unalleviated pain and distress. Compliance with the Animal Welfare Act is monitored by periodic, unannounced inspections by the Animal Plant and Health Inspection Service (APHIS). Deficiencies identified during annual, unannounced inspections by the APHIS can lead to severe institutional penalties, including fines and the suspension/revocation of an Institution's registration with the USDA. Note that all inspection results are also available on the Internet for public viewing following Freedom of Information Act requirements.

- 3) Public Health Service - The Public Health Service Policy on the Humane Care and Use of Laboratory Animals states that, "to receive NIH awards for projects involving animals, an institution must have an approved animal welfare **Assurance Statement** on file with the **Office of Laboratory Animal Welfare** (OLAW, formerly OPRR/Office for the Protections from Research Risks) within the Office of Extramural Research (OER). This statement commits the institution to:
- The Animal Welfare Act
  - The Guide for the Care and Use of Laboratory Animals
  - The U.S. Government's Interagency Research Animal Committee (IRAC) "Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training"
  - Other applicable laws and standards

The Assurance Statement describes the mechanism used by the institution to determine compliance with laws and standards, and it identifies the membership and responsibilities of the institution's animal care committee. When accepted by NIH, an Assurance Statement is approved for a one to five year period. The "PHS Policy" requires Institutional Animal Care and Use Committees to approve the care and use of animals as proposed in PHS grant applications before funds will be awarded. Animal Care and Use Committees also are required to conduct semiannual assessments of the University's Animal Care and Use Program, using the Guide as a basis for evaluation. Significant deficiencies in the animal care and use program must be identified and the University must develop an approved plan and schedule for correction of such deficiencies. The University's failure to comply with these policies may lead to various penalties, including the termination of PHS support for all projects involving animals at the university. The "OU Assurance of Compliance with Public Health Service Policy on Humane Care and Use of Laboratory Animals" can be obtained by contacting the IACUC office.

- 4) State Laws. In addition to federal regulations, Michigan is one of the few states which has laws governing pet shops, animal shelters, dog pounds, riding stables, and research institutions. Two Michigan departments enforce these regulations. The Michigan Department of Agriculture inspections cover dogs and cats. The Michigan Department of Public Health regulations cover all living vertebrates.

**f. Independent National Regulatory Bodies and Professional Groups**

- 1) **Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC)** AAALAC is currently the only non-profit organization whose mission is to assess the animal care and use program of research institutions on a voluntary basis. After an initial assessment and accreditation, accredited institutions are

required to submit an annual report outlining any changes in the animal care and use program. Every three years, AAALAC performs a site visit of accredited institutions, using a program description as their written guide to the program. Like OLAW, AAALAC requires the use of the Guide for the Care and Use of Laboratory Animals as the primary instruction manual for programs, policies, and facilities.

- 2) **American Association for Laboratory Animal Science (AALAS)** Membership in AALAS is only limited to personnel actively engaged in laboratory animal science. As the major laboratory animal science organization, AALAS has many important roles. Among the most active include: Publication of the periodicals *Comparative Medicine* and *Contemporary Topics in Laboratory Animal Science*. Sponsorship of a training and certification program for laboratory animal technicians, which leads to the nationally recognized status of Assistant Laboratory Animal Technician (ALAT), Laboratory Animal Technician (LAT), and Laboratory Animal Technologist (LATg).

The humane care and use of animals is of paramount importance to OU. As part of the University's commitment to and the assurance of providing humane care and use of animals, individuals who may have specific concerns about animal care and treatment are encouraged to report their observations of deficiencies. Individuals may refer to Policy Number 10.2 of this handbook for further information and instructions concerning the reporting of deficiencies.

## 10.2 Reporting Deficiencies in Animal Care and Use

The humane care and use of animals is of paramount importance to OU. The treatment of University-owned animals should be of high quality and in compliance with all federal, state, and local regulations. The law requires that all persons involved or in any way associated with the use of animals in research or teaching know how to report deficiencies in animal care and treatment. Statutory authority for this instruction is found in the 1985 Amendments to the Animal Welfare Act Title 7, United States Code, Section 2131-2156, PL-99-198. The act requires that "...training for scientists, animal technicians, and other personnel involved with animal care...shall include...methods whereby deficiencies in animal care and treatment should be reported." There are no restrictions on who can report an alleged incident. Anyone who has knowledge of such a deficiency is obligated to report it to the proper OU officials immediately. Under no circumstances will reporting such incidences in good faith be detrimental to an individual's standing within the University.

### a. Allegations of Animal Mistreatment and Non-Compliance

- 1) Mistreatment: The wrongful or abusive physical or psychological treatment of an animal.
- 2) Non-compliance: Not following the established procedures, policies, or protocols. These items may include animal use without approval, deviation from an approved protocol, and facility, management, procedural, or other related deficiencies that reflect on the quality of care and use of animals.

### b. Reporting Procedures

Concerns regarding misconduct associated with the care and treatment of animals may be reported to the IACUC Chairperson, any IACUC committee member, the University veterinarian, the Vice Provost for Research, or the Animal Research Facility Manager. Reports should be as specific as possible, *i.e.*, date, time, species involved, animal/protocol identification number, and

the names of University personnel involved. Written reports should be addressed to the IACUC Chairperson or an individual in the following manner:

Chairperson or Member (name), IACUC  
Grants Contracts and Sponsored Research  
5<sup>th</sup> Floor Wilson Hall  
Oakland University  
Rochester, Michigan 48309-4401  
PRIVATE and CONFIDENTIAL

Reports of care and use deficiencies may also be given verbally to the IACUC Chairperson, any IACUC committee member, the University Veterinarian, the Vice Provost for Research, or the Animal Research Facility Manager. A current list of IACUC members may be obtained from the Office of Grants Contracts and Sponsored Research at (248)370-2762.

OU's **Report of Deficiencies in Animal Care or Use** form is available in the Biomedical Research Support Facility (BRSF), or by requesting a form from any BRSF personnel. The form is also available online at, <http://www.oakland.edu/research>, under Regulatory Compliance.

#### **c. IACUC Response to Deficiencies Report**

The receipt of a written or verbal report of animal care and use deficiency by the IACUC will be immediately brought to the attention of the Vice Provost for Research, who is also the Institutional Official, and the IACUC Chairperson. These individuals will select an additional committee member to constitute a subcommittee to investigate and, where concerns are substantiated, bring about the correction of the reported deficiency. Reports and corrective actions will conform to all applicable University policies. At the next regularly scheduled IACUC meeting, the subcommittee will describe the reported deficiency and the corrective action that has been taken or recommended. If, and when, a letter reporting a deficiency is forwarded to an outside regulatory agency (*i.e.*, OLAW, AAALAC), funding agency (through the Office of Grants Contracts and Sponsored Research), or in other instances where notification seems appropriate as determined by the committee, a letter will also be forwarded to the department chair affiliated with the protocol in question. Details of any reports or allegations of deficiencies, findings, or recommendations of the IACUC, as well as administrative or legal actions taken by the committee are considered privileged information and may be released only through official channels, or as required by law.

#### **d. Protection**

IACUC and subcommittee members will remain honor-bound to respect report confidentiality. Individuals generating a deficiency report shall not be discriminated against or be subject to any reprisal for generating the report. Individuals who desire anonymity may be certain that the IACUC will handle a deficiency report in confidence to the extent permitted by law. Neither administrative action nor retribution of any kind may be taken against a person making a good faith report of deficiencies. This is in accordance with public law [9 CFR, Part 2, Subpart C 2.32 (c) (4)]. According to the *Animal Welfare Act*, "No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of the Animal Welfare Act."

#### **e. Consequences**

Principal investigators will be responsible to assure that all personnel involved in research activities under their direction are aware of the above procedures. Willful mistreatment or abuse of animals may be grounds for suspension of all animal use activities or protocols involved, or other disciplinary actions. Disciplinary action may be appealed through existing procedures.

### **10.3 Use of Vertebrate Animals as Subjects in Research or Instruction**

#### **a. Rationale**

The purpose of this policy is to ensure the humane use and care of vertebrate animals used in research, instruction, and testing. All applicable laws, regulations, policies, principles, and standards, affecting such use, must be adhered to. This includes voluntary professional standards and accreditation.

#### **b. Policy**

OU requires high standards of humane care and use of laboratory animals and assures compliance with federal and state regulations, and accreditation guidelines. This applies in all situations and activities of the university in which vertebrate animals are used. Animals may not be used in research, testing, or instruction without prior approval from the Institutional Animal Care and Use Committee (IACUC). It is necessary that investigators include in their protocol measures to eliminate or minimize any unnecessary pain and discomfort to animals. Under certain circumstances alternatives to the use of live animals must be considered.

#### **c. Regulations and Standards**

Rules and regulations, in addition to promoting the humane care and use of animals utilized in research, can be positive from the investigator's standpoint. Many times inspection of facilities can help resolve problems and provide justification for facility improvements. Favorable inspection reports can also help assure concerned citizens that research animals are well cared for and that facilities are appropriate.

#### **d. Federal Animal Welfare Act**

The Animal Welfare Act was enacted in 1966 and has been amended several times. Provisions of the Act are monitored by the United States Department of Agriculture (USDA). Representatives of the USDA make periodic unannounced inspections to ensure compliance with regulations for housing, feeding, cleanliness, ventilation and veterinary care. They also review adherence to standards for postoperative care and for use of analgesic and anesthetic agents for potentially painful procedures.

Under the Animal Welfare Act, the University is required to have an Institutional Animal Care and Use Committee (IACUC) to oversee animal care and the use of animals.

#### **e. U.S. Public Health Service Policy**

The U.S. Public Health Service (PHS) has a Public Health Service Policy on Humane Care and Use of Animals. The policy applies to any institution receiving funding from any agency of the PHS including the National Institutes of Health (NIH) and a number of other government agencies. Institutions receiving PHS funding must follow the recommendations of the Guide for

the Care and Use of Laboratory Animals. The PHS policy and guidelines apply to all species of vertebrate animals. The University is required to have an assurance statement on file with the NIH's Office for Protection from Research Risks (OPRR) stating how PHS policy is implemented. The Health Research Extension Act of 1985 codifies requirements for the U. S. Public Health Service Policy on the Humane Care and Use of Laboratory Animals.

**f. Voluntary Professional Standards - AAALAC Accreditation**

Oakland University's Animal Care and Use Program received accreditation by AAALAC International on June 19, 2010. This accreditation represents an independent peer review process which is voluntarily sought by institutions. The accreditation standards are rigorous. AAALAC accreditation is viewed by the PHS and other public and private funding sources as the best means to demonstrate that a grantee is supported by an animal care and use program maintaining high standards.

**g. State Laws**

In addition to federal regulations, Michigan is one of the few states which has laws governing pet shops, animal shelters, dog pounds, riding stables, and research institutions. Two Michigan departments enforce these regulations. The Michigan Department of Agriculture inspections cover dogs and cats. The Michigan Department of Public Health regulations cover all living vertebrates.

**h. Principles for Animal Care**

The Institutional Animal Care and Use Committee (IACUC) endorses the United States Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. These principles are also endorsed by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International.

- 1) The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et seq.) and other applicable federal laws, guidelines, and policies.
- 2) Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- 3) The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.
- 4) Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in humans may cause pain or distress in other animals.
- 5) Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or



other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

- 6) Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- 7) The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.
- 8) Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
- 9) Principal investigators must take responsibility for the appropriate training of their research staff in the humane care and use of laboratory animals, ensuring that they are qualified to perform their duties, and that they understand their obligations to comply with all relevant regulations and the specifics of the approved protocol. Documentation of this training may be requested by regulatory and accrediting agencies or by the institution.
- 10) Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

#### **10.4 Animal Care and Use Training and Education Program**

##### **a. Rationale**

Public trust demands those individuals who do research, testing, or teaching with animals use humane, ethical, and scientifically sound methods. The primary goal of training is to provide individuals with basic knowledge and to reinforce attitudes and behaviors that help to ensure humane animal care and use. The Animal Welfare Act (AWA) and the Public Health Service Policy (PHS) require research institutions to provide basic training and to ensure that anyone who cares for and/or works with laboratory animals has the appropriate training or experience relevant to their job responsibilities. Institutions accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International must also provide training programs and ensure the qualifications of personnel. Training ensures; that OU Animal Care and Use Program will remain in compliance with applicable laws and accreditation expectations, the University will reap the benefits of savings in time, effort, and resources because trained employees usually have higher productivity and fewer errors than untrained personnel, and properly trained individuals will recognize when unwanted variables or health issues might affect the research data allowing them to promptly intervene to minimize any negative impact.

##### **b. Policy**

Researchers must hold an advanced degree (i.e., MD, PhD, DVM, etc.) in order to serve as principal investigators. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. All protocols submitted to the Institutional Animal Care and Use Committee (IACUC) for review must describe experience/training personnel have had or will have with the specific animal models. The IACUC then performs an assessment of the personnel's ability to work humanely with animals. The IACUC may assign specific training to personnel as a condition of their approval. Adequate arrangements shall be made for in-service training, including the proper and humane care and use of laboratory animals. All animal protocols involving the use of potentially hazardous agents are assessed by the IACUC and submitted to the appropriate committee for review and approval prior to a protocol receiving full IACUC approval. The principal investigator is responsible for providing training for staff when working with hazardous agents and overseeing all work to confirm that safety committee mandates are followed. All individuals named on a protocol must complete the required CITI Program training courses as specified by the IACUC.

#### **c. Training**

The OU IACUC requires that all Principal Investigators and key personnel complete the assigned modules in the online CITI Program training accessible from the IACUC website. [http://www2.oakland.edu/research/research\\_new/pages/pages.cfm?page\\_id=29](http://www2.oakland.edu/research/research_new/pages/pages.cfm?page_id=29)

#### **d. Hands on Animal Care and Instruction**

Hands on training for first time researchers or key personnel regarding the handling of a specific species can be scheduled by contacting the Animal Research Facility Manager at 248-370-4440.

### **10.5 Transport, Care and Use of Non-Oakland Owned Laboratory Animals on the Oakland University Campus**

#### **a. Rationale**

The care and use of laboratory animals procured by OU for teaching, research, and related activities are governed by policies designed to keep the University in compliance with all relevant external regulations for the humane care and treatment of laboratory animals. Should OU investigators collaborate with or provide services to outside institutions that require the transportation of non-Oakland owned laboratory animals then the procedures set forth here must be followed so that the animals involved are treated humanely, that the associated risks are managed properly, and that OU remains in compliance with all relevant external regulations.

*The Guide for the Care and Use of Laboratory Animals* states that animal transportation "should be planned to minimize transit time and risk of zoonoses, protect against environmental extremes, avoid overcrowding, provide food and water when indicated, and protect against physical trauma." Some transportation related stress is inevitable, and for animals in transport it is important to maintain their health status by avoiding exposure to potential pathogens, prevent injury, and reduce stressors such as temperature extremes, odors, excessive noise, and confrontations with other animals. Animal transportation requires attention to detail to ensure safety and well being for the personnel in areas where the animals must pass. Human health concerns include allergies of animal origin, injury from escaped animals, and exposure to hazards such as microorganisms, chemicals, or radioactive materials if they are used.

## b. Procedures

To ensure that regulations and concerns are addressed regarding animal transport, the following general guidelines have been established for OU:

- 1) All methods of transporting animals must provide for the health and welfare of the animals.
- 2) Transportation of animals must be done in a direct and timely manner, avoiding public areas as much as possible. In selecting the route, care should be taken to utilize the least congested areas and to avoid human areas whenever possible.
- 3) Animals must not be transported with any other animals, substance, or device that may potentially cause injury to the animal being transported.
- 4) Enclosures containing animals must be secure and carefully handled. The enclosures must be maintained in a manner that will prevent them from tipping or falling and must be handled in a manner that will minimize any physical trauma or distress to the animals.
- 5) Temperature extremes must be avoided when animals are transported. While some types of caging will insulate animals, exposure to extreme ambient temperatures can have adverse effects. When temperatures fall below 40°F or above 85°F, special precautions, in addition to those used in the environmentally controlled vehicles, may need to be taken.
- 6) The USDA regulations must be followed when transporting animal species covered under the Animal Welfare Act (AWA). [Note: the AWA and the [Guide](http://www.oakland.edu/research) can be accessed at <http://www.oakland.edu/research> under Regulatory Compliance]. These animals include: dogs, cats, non-human primates, calves, sheep, goats, pigs, rabbits, guinea pigs, hamsters, and other mammals not specifically excluded (exclusions are laboratory mice, rats and birds). Transportation of animals must also comply with all applicable local and state laws and regulations.
- 7) Animals should be transported in covered or opaque cages, carriers, or containers. These primary enclosures must be constructed of materials that can either be sanitized or disposed of, and must be designed to prevent the spread of fomites, microorganisms, chemicals, or radioactive materials if indicated. The containers shall:
  - i) Be escape proof. There must be a means to prevent unintended opening, such as a latch or locking mechanism, tape, rubber band or a box-within-a-box. This applies to transport within the hallways, as well as between buildings.
  - ii) Provide adequate ventilation. (Note: stacking rodent cages or using enclosed impermeable containers or trash bags with air holes does not provide adequate ventilation).
  - iii) Provide food and a source of water when rodents will be held within the transport container for longer than 4 hours.
  - iv) Use the same density requirements for general animal housing as described in the [Guide for the Care and Use of Laboratory Animals](#).
  - v) Protect the transporter from exposure to licks, bites, scratches or other animal contact during transit.

- 8) Cargo areas of vehicles used in the transportation of animals must be cleaned and disinfected as needed to prevent contamination of future animal deliveries. Sanitation of the interior of the truck can occur either after transporting the contaminated animals/equipment or prior to transporting the next shipment of animals/equipment. The interior floor and lower walls or any surface that could be in contact with the animals/equipment should be sanitized with disinfectant.
- 9) Investigators may apply for an exception with the IACUC office for the transportation, receipt and shipment of animals if they have requirements that differ from these guidelines.

### **c. Related Policies and Forms**

The appropriate use of Personal Protective Equipment (PPE) protects both research animals from human pathogens and cross contamination of humans with animal pathogens. People who are in direct contact with research animals should cover their street clothing and exposed body surfaces with PPE to reduce the risk of pathogen contamination through contact or aerosolization. The appropriate disposal of PPE is also necessary so that the PPE does not act as a fomite for transmitting pathogens.

Washing of hands following live animal transportation is an important adjunct to the use of exam gloves or in place of exam gloves for preventions of the spread of infectious organisms or other contaminants to both personnel and animals. While the use of exam gloves will greatly decrease the spread of contaminants from a person's hands, they will not completely eliminate this transfer due to micro-breaks in glove materials, regardless of the type of glove used. For effective hand washing, antimicrobial soaps or alcohol-based hand rubs (60-95% alcohol) are recommended for use (NIH Manual 3044-2: Guidelines for Personnel Protection and Minimum Requirements for Protective Clothing in Animal Facilities: revised 3/9/05).

The Animal Research Facility Manager is the designated representative and is responsible for oversight of these animal transportation guidelines, can grant exceptions when it is considered in the best interest of the animal(s), and is the contact for information concerning the transportation, receipt, and shipment of animals. Conflicts regarding animal transportation issues will be resolved by the Animal Research Facility Manager or by the Institutional Animal Care and Use Committee (IACUC).

## **10.6 Contacts**

For questions regarding assistance with an application, for questions regarding hands on training for animal care, and for regulatory questions, call the Animal Research Facility Manager @ 248-370-4440

## Chapter 11: Export Controls

Since 9/11 the federal government has dramatically increased enforcement of “export control” regulations to prevent the transfer of potentially threatening information, technology and materials to certain individuals and countries within or outside of the United States. Universities have become a focus of interest because of the multiple activities across campus that may deal with sensitive technology, information or material; the large population of foreign nationals; the cutting edge research in engineering and science, and the open culture of the academe. Non-compliance with Export Control regulations can result in severe criminal and civil penalties for the individual or the University. These include fines or incarceration for individuals, forfeiture of materials or data, and loss of research privileges for the individual and University.

### 11.1 Risk Areas

Export controls regulations apply to a number of activities across the Oakland University (OU) campus. To the extent that the University activities involve purchasing equipment, shipping equipment abroad, material transfer, or teaching or training foreign students on campus, or foreign colleagues abroad how to use equipment, export control restrictions may apply.

Export control regulations also may apply to OU faculty who travel abroad and visiting faculty who may have access to controlled research or technology on OU’s campus. These regulations include:

- 1) Travel to conferences or other academic activities with:
  - Laptops
  - Encryption products
  - Data/technology
  - Blueprints, drawings, schematics
- 2) Supplying certain technologies/data at a “closed” conference or meeting (not open to all technically qualified members of the public, and attendees are not permitted to take notes)
- 3) Money transactions and the exchange of goods and services in certain countries
- 4) Travel to sanctioned/embargoed countries
- 5) Doing business with certain people or entities

### 11.2 Exemptions and Exclusions

The Department of Commerce’s Export Administration Regulations (EAR) and the Department of State’s International Traffic in Arms Regulations (ITAR) allow for specific exclusions and exemptions for university research. The most commonly applied are:

- 1) Fundamental Research  
As used in the export control regulations, includes basic or applied research in science and/or engineering at an accredited institution of higher learning in the United States where the resulting information is ordinarily published and shared broadly in the scientific community. Fundamental research is distinguished from research which results in

information which is restricted for proprietary reasons or pursuant to specific U.S. Government access and dissemination controls. University research will not be deemed to qualify as Fundamental Research if: (1) the University or research accepts any restrictions on the publication of the information resulting from the research, other than limited prepublication reviews by research sponsors to prevent inadvertent divulging of proprietary information provided to the researcher by sponsor or to insure that publication will not compromise patent rights of the sponsor; or (2) the research is federally funded and specific access and dissemination controls regarding the resulting information have been accepted by University or the researcher.

- 2) **Public Domain**  
(22 CFR 120.11) means information that is published and that is generally accessible or available to the public: (1) through sales at newsstands and bookstores; (2) through subscriptions which are available without restriction to any individual who desires to obtain or purchase the published information; (3) through second class mailing privileges granted by the U.S. Government; (4) at libraries open to the public or from which the public can obtain documents; (5) through patents available at any patent office; (6) through unlimited distribution at a conference, meeting, seminar, trade show or exhibition, generally accessible to the public, in the United States; (7) through public release (i.e., unlimited distribution) in any form (e.g., not necessarily in published form) after approval by the cognizant U.S. government department or agency; and (8) through *fundamental research*.
- 3) **Employment Exclusion**  
No license is required to share information with a foreign person who is full-time, *bona fide* university employee and has a permanent address in the US while employed, provided that that person is not a national of a federally designated country and is advised in writing not to share controlled information with other foreign persons.

The “fundamental research” and “public domain” and Employment exemptions/exclusions prevent most research activities conducted on campus to be outside of the export control regulations. When research does meet the criteria for these exemptions/exclusions, foreign students and foreign nationals have free access to all aspects of the research. However, it has become increasingly common for the federal government and commercial sponsors to insert export control related clauses (i.e. pre-publication approval, citizenship requirements or nondisclosure agreements) into contracts and agreements for sponsored research, vendors and contractors, which eliminate the exemptions from being applicable. In these cases, a broad range of exports controls regulations may apply. If research is to continue, the University may apply for a special license from the Commerce, State or Treasury Department, which is a long and costly process and is often denied.

Other University activities such as Purchasing and Risk Management, Human Resources, or International Students and Scholars, for example, are not under the umbrella of these exclusions and people and materials must be screened and the regulations adhered to.

### **11.3 Sanctions and Penalties: Individual and Institutional**

In addition to fines and prison terms under criminal and civil export control sanctions, there are administrative sanctions (including denial of export privileges and exclusion from practice), statutory sanctions, seizure and forfeiture, cross-debarment, denial of licenses or approvals, and suspensions of the right to contract with the United States Government.

**Criminal Sanction and Penalties:**

- Up to \$1 million for a university
- Up to \$1 million for an individual per violation
- Up to 10 years imprisonment

**Civil Penalties:**

- Seizure and forfeiture of controlled item(s)
- Up to a \$5000,000 fine per violation
- Revocation of exporting privileges

In 2008, 145 individuals were prosecuted by the Department of Justice for export control violations. Prosecutions occurred for transferring information, technology or materials to countries as diverse as Iran, Sweden, Japan and Canada, and for the export of such “dual use” equipment as ball bearings and global positioning units. .

Among those convicted of violating export control regulations was a Professor Emeritus at the University of Tennessee who was convicted of 15 counts of violating the Arms Export Control Act for transferring technical information, relating to plasma technology, designed to be deployed on the wings of Unmanned Aerial Vehicles that he carried via computer to China and emailed to colleagues in Iran.

The Department of the Treasury also keeps a list of Sanctioned Countries to which no financial transfer or services may be made. These include Cuba and Syria. The FBI has initiated divisions dedicated to export control regulations and have become frequent visitors to University and College campuses.

Universities must show due diligence in the oversight of campus activities restricted by export control regulations and are responsible for ensuring that the University is in compliance with these regulations and to be available for federal agency inquiries or investigations.

Because the regulations conflict between government agencies and are broad and complicated to deal with on an individual basis, it is important that faculty contact the Office of Grants, Contracts and Sponsored to discuss any research that has a specific military application or a potential military use at 248-370-4924.