

Policies and Procedures for Grants and Sponsored Projects



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I. FEDERAL POLICY MANDATES

A-21 http://www.whitehouse.gov/omb/circulars_a021_2004

A-110 http://www.whitehouse.gov/omb/circulars_a110/

A-133 <http://www.whitehouse.gov/sites/default/files/omb/circulars/a133/a133.pdf>

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II. PRINCIPAL INVESTIGATOR ELIGIBILITY & ASSURANCE

Full-time Lesley University Employees acting in their capacity as a University employee are eligible Principal Investigators. Emeriti may be a Co-Principal Investigator as long as a full-time faculty member has been identified as their Co-Principal Investigator. Part-time faculty may also undertake the role of Co-Principal Investigator when the other Co-PI is a full-time LU Faculty member.

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III. LIMITED SUBMISSIONS

POLICY STATEMENT

Some funding programs limit the number of submissions that can be made at any one time from one university or college. Therefore, we have established the following guidelines so that all concerned will be treated fairly. Remember, if Lesley University submits more than the allowable number of proposals in a limited submission program, it is likely that all proposals from the University will be disqualified!

PROCEDURES

In cases in which a sponsor allows only a limited number of proposals to be submitted, we will select proposals according to the following process:

1. Approximately six weeks before the application deadline, the Office of Grants and Sponsored Projects (OGSP) grants officer will solicit letters of intent to apply and project justification of no longer than one page from each prospective applicant (faculty, librarian, administrator, and/or Advancement grants officer).
2. The applicants' materials will then be forwarded to the OGSP for review and ranking.
3. The OGSP grants officer will notify all candidates of their status. If the first candidate should decide to forgo applying, then OGSP will notify the candidate whose notification was ranked second, and so forth.
4. The nominees should work with the OGSP and/or Advancements grants officer to complete the proposals.

CURRENTLY-KNOWN LIMITED-SUBMISSION PROPOSALS

<http://www.daviseducationalfoundation.org>

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf12505&org=NSF

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf07540&org=NSF

<http://www.nsf.gov/pubsys/ods/getpub.cfm?nsf02178>

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf09533&org=NSF

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf10581&org=NSF

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http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf11550&org=NSF

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf11566&org=NSF

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf08558&org=NSF

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf10544&org=NSF

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf12518&org=NSF

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf08600&org=NSF

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf12529&org=NSF

http://www.nsf.gov/pubsys/ods/getpub.cfm?ods_key=nsf0451

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IV. MISCONDUCT IN RESEARCH

Under the Policy and Procedural Guidelines for Misconduct in Research and Scholarship, allegations of misconduct in research and scholarship are directed to the Dean of the appropriate College and the Provost. The University assumes responsibility for resolving allegations and investigating incidents on misconduct by its faculty, staff, and students. These responsibilities exist regardless of whether the activity is funded by federal, state, or private sources, or are the result of unfunded efforts. The full text of the policy is below:

The creation and dissemination of knowledge are primary missions of the University. Accordingly, the University should foster an environment in which research flourishes. Such an environment requires the integrity of faculty, students, and staff who conduct research and scholarship. Furthermore, faculty, investigators, and other supervisors need to ensure the integrity of research and scholarship conducted under their direction.

A. Policy

At Lesley University, misconduct in research and scholarship is defined as: The intentional fabrication or falsification of data, research procedures, or data analysis; plagiarism; or other fraudulent activities in proposing, conducting, reporting, or reviewing research. Willful failure to comply with federal, state, or university requirements a) for protecting researchers, human subjects, and the public during research and b) concerning the humane treatment of animals used in research. Use of research funds, facilities, or staff for unauthorized and/or illegal activities.

B. Clarifications

Hereinafter "misconduct" means misconduct in research and scholarship as defined above. Misconduct does not include honest error or honest differences in interpretation or judgments of data. This policy pertains to original research and scholarship only and is not intended to replace other policies dealing with academic conduct, such as integrity in class or course work.

"Inquiry" means information gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants investigation. "Investigation" means the formal examination and evaluation of all relevant information to determine if misconduct has occurred.

C. Procedures

The Dean of a college and the Provost may receive, typically in writing, allegations of misconduct in research and scholarship. However, the Provost of the University, through the University Deans, is ultimately responsible for all research programs and activities conducted at the University. Therefore, the Provost shall be informed by the Deans of all allegations of misconduct in research and scholarship. Furthermore, the Provost shall consult with the University's Attorney on all inquiries and investigations, and is responsible for directing inquiries into and investigations of misconduct in research and scholarship, and in meeting all reporting requirements established by federal and non-federal agencies.

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The procedures of this policy are not exclusive of other mechanisms for the review of misconduct. In the case of review of allegations of misuse of funds, the University's Internal Auditor, and in some cases outside auditors, shall investigate and report to the proper administrators. In the case of alleged illegal activities, the Provost retains the power to direct investigations, take interim measures prior to or during any inquiry or investigation to preserve state property or resources, and request reports on alleged violations. Where an investigation of misconduct under this Policy may be duplicative, and where issues of the proper conduct of scientific research are lacking, the Provost may decide not to conduct an investigation under this policy.

D. Administrative Procedures

1. An inquiry will be made immediately into allegations or evidence of possible misconduct. Inquiries will be conducted by the Dean of the affected college, or, if appropriate, the Provost, or their designees.

An inquiry should be completed within 60 calendar days of its initiation unless the Provost rules that circumstances warrant a longer period. At the commencement of the inquiry, the affected individuals will be informed about the nature and proposed extent of the inquiry. A written report shall be prepared that documents the evidence received, including summaries of interviews and the conclusions reached. The individuals against whom the allegation was made shall be kept informed of the inquiry procedure and be given a copy of the report of inquiry. If they comment on this report, their comments will be made part of the record. If the inquiry takes longer than 60 days, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period and record of agreement to the extension by the Provost and the individual's against whom the allegations are made.

Persons who have reported apparent misconduct will be protected to the extent possible under Commonwealth law.

The affected individual's will receive confidential treatment to the extent possible under Commonwealth law; they are also entitled to a prompt and thorough inquiry, and they will have an opportunity to comment on allegations and the findings of the inquiry.

If it is determined that an investigation is not warranted, records will be maintained for one year in sufficient detail to permit subsequent assessment of that determination.

A decision on whether to proceed to a formal investigation shall be made by the Provost in consultation with the college Dean. If an investigation is deemed unwarranted, the Provost and College Dean will take steps to protect the party or parties who made good faith allegations, and the individual(s) charged with misconduct. Also, the College Dean and the Provost will take such steps as they deem appropriate to repair any damage done to the reputation of individuals falsely accused.

In case of apparent false and malicious accusations, an inquiry will be initiated by the Provost and Dean of the accuser(s). The accused person may also request such an inquiry.

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2. If warranted, an investigation will begin following the inquiry as described under 1. Investigations will begin, within 30 days of the completion of the inquiry, by a committee appointed by the Provost, and comprised of at least three faculty members familiar with the research or scholarship included in the alleged misconduct and at least one faculty member whose academic appointment is outside of the University of the accused individual(s).

The investigation will include examination of all pertinent documentation, publications and correspondence, and any memoranda related to telephone calls. Whenever possible, interviews will be conducted with all individuals involved in making the allegation, or against whom the allegation is made, or other individuals who might have information pertinent to the allegations. Summaries of the interviews will be prepared, provided to the interviewed parties for comment or revision, and included as part of the investigation file. Precautions will be taken to prevent real or apparent conflicts of interest on the part of those involved in the investigation.

Diligent efforts will be made, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed. Documentation will be prepared and maintained to substantiate the investigation's findings.

An investigation of misconduct will be completed within 120 days of its initiation. This includes conducting the investigation, preparing a report of the findings, and making the report available for comment to the subjects of the investigation.

When allegations of misconduct in research and scholarship involve the use of federal funds, the following additional steps will be followed:

- The College Dean or Provost will notify the relevant federal agency prior to an investigation and within 30 days following the completion of an inquiry. If there is indication of criminal violations, the College Dean or Provost will notify the relevant federal agency within 24 hours of obtaining appropriate evidence.
- When appropriate, documentation of the investigation's findings will be made available to a relevant federal agency.
- The University will be responsible for notifying relevant federal agencies if any of the following exist during an inquiry or investigation: an immediate health hazard, an immediate need to protect extramurally obtained funds or equipment, an immediate need to protect any parties involved; or if the incident is going to be reported publicly, in the case of possible criminal violation.
- Interim administrative actions will be taken, as appropriate, to protect federal funds and insure that the purposes of federal financial assistance are carried out.
- The University will keep the relevant federal agency apprised of any developments during the course of the investigation which may affect current or potential funding for

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the individual under investigation or are necessary for the federal agency to protect the public interest.

- The report of the investigation, completed within 120 days, will be submitted to the relevant federal agency along with the final outcome of the investigation.

While the University is primarily responsible during the period of inquiry and investigation, a relevant public agency may perform its own investigation at any time prior to, during, or following the University's investigation and may impose sanctions determined by its own investigation.

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V. CONFLICT OF INTEREST

Under the Financial Disclosure Policy for Federally-Funded Projects, faculty members participating in federally sponsored projects must disclose whether or not they have external affiliations that may constitute a conflict by falling within criteria outlined in the policy. Positive disclosures will be reviewed by a Conflict Review Committee consisting of the Provost, the Assistant Attorney General, and the Director of the Office of Sponsored Projects.

45 CFR Part 94 as any public or private entity or organization (excluding a Federal agency) (1) that submits a proposal for a research contract whether in response to a solicitation from the PHS or otherwise, or (2) that assumes the legal obligation to carry out the research required under the contract. 42 CFR 50.603; 45 CFR 94.3.

Lesley University Conflict Of Interest Policy for Grants and Sponsored Projects

University personnel are required to adhere both to federal and state regulations regarding conflict of interest in relation to sponsored projects. The guidelines below describe University policies and procedures regarding compliance.

For more detailed information, the NSF regulations can be found at http://www.nsf.gov/pubs/policydocs/pappguide/nsf08_1/aag_4.jsp.

NIH regulations can found at http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm#_Toc54600065.

A **Conflict of Interest** may exist when a significant financial interest could directly affect the design, conduct, or reporting of an investigator's research. "**Investigator**" includes the investigator's spouse or domestic partner, dependent children, or anyone related by blood, adoption, or marriage.

"**Significant financial interest** means, except as otherwise specified in this definition: "(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:'

- (i) "With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition,
- (ii) remuneration includes salary and any payment for services not otherwise identified as salary (*e.g.*, consulting fees, honoraria, paid authorship, travel reimbursement); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value; "
- (iii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or the Investigator (or the

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Investigator's spouse or dependent children) holds any equity interest (*e.g.*, stock, stock option, or other ownership interest); or
(iv) Intellectual property rights (*e.g.*, patents, copyrights), royalties from such rights, and agreements to share in royalties related to such rights. If an individual is **debarred or suspended**, she or he is ineligible to receive federal funds. Any individual meeting these conditions must immediately notify the OGSP and is precluded from receiving federally-funded grants or contracts or from being paid with federal funds.

An investigator who has significant financial interests that could affect her/his research must submit a **University Financial Disclosure Statement** to the OGSP grants officer or the Associate Provost. All significant financial interests must be disclosed before a proposal is submitted, and disclosures must be updated annually or as new significant financial interests occur. The Associate Provost shall conduct an initial review to determine whether a potential conflict exists. If a potential conflict is revealed, then the disclosure and supporting materials will be referred to the Associate Provost of Academic Affairs. The Associate Provost will work with the investigator(s) to develop a written conflict management plan that details steps to manage, reduce, or eliminate conflict of interest.

This written **Conflict Management Plan** will be submitted to the Provost and upon approval by the Provost, signed by the investigator(s) and the Provost. Investigators dissatisfied with the Plan may appeal to the Provost, whose decision is final. The Conflict Management Plan shall be kept on file with the investigator's funding application materials. This Plan must be approved before any award funds can be expended. Violations, such as willful concealment of financial interests, may result in sanctions.

Records of financial disclosures and of actions taken to manage conflicts of interest shall be kept in strictest confidence and retained by the OGSP until seven years after the termination of the award, or the resolution of any government action involving those records. Records will not be provided to sponsors unless the agency requires it, the agency submits a written request, or there is a documented instance of research misconduct. The Associate Provost will be responsible for communicating with sponsors. The investigator will be notified any time such records are released.

Despite the University's best intentions and efforts, departures from accepted standards of integrity and honesty may occur. Thus, the University must have policies that define misconduct in research and scholarship, procedures for the inquiry into an investigation of alleged misconduct, and guidelines for the prosecution of proven misconduct.

The University assumes responsibility for resolving allegations and investigating misconduct in research and scholarship by its faculty, staff, and students. These responsibilities exist regardless of whether the activity is funded by federal, state, or private sources, or is the result of unfunded efforts. This document contains policy and procedures for addressing misconduct in original research and scholarship.

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VI. POLICY OF USE OF HUMAN SUBJECTS IN RESEARCH (IRB)

1.0 INSTITUTIONAL RESPONSIBILITIES

1.1. Campus policies and federal requirements regarding research with human subjects are implemented by the Institutional Review Board for the Protection of Human Subjects in Research (IRB). The members of the IRB are appointed by the Associate Provost. Composition and appointment of the IRB is described in Section 17.0.

1.2. The protection of human subjects from undue risks and deprivation of personal rights and dignity can best be achieved through consideration of three issues: 1) that subject participation is voluntary, indicated by free and informed consent (the subject is free to withdraw at any time without jeopardy and may request that his/her data be destroyed); 2) that the degree, nature, and management of risk to the subject and the researcher have been delineated explicitly by the researcher; and 3) that appropriate balance exists between potential benefits of the research to the subject and/or to society and the risks assumed by the subjects.

1.3 The IRB has the ultimate responsibility to determine risk with regard to human subject research and to approve or not approve such research performed under the sponsorship of the University or its auxiliaries.

2.0 SCOPE OF THE REVIEW

2.1 The institution must review biomedical and behavioral research involving human subjects conducted at or sponsored by the University in order to protect the rights of human subjects of such research. Activities which are not research but which nevertheless involve people are not covered by this policy, but rather by other appropriate codes of conduct. Research is defined by the *Uniform Federal Policy for the Protection of Human Subjects* as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge." Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. Research activities involving people are divided into three categories:

A. *Exempt Research.* The IRB will review all protocols involving human subjects and determine whether the proposed research is exempt. Researchers should fill out the application and designation of exempt status will be determined by the Chair of the IRB if warranted.

B. *Expedited Review: Research Involving 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. Research in this category may receive expedited review (see Section 5.0). Researchers should submit proposals in the same manner as for proposals involving more than minimal risk (described in Sections 3.0 and 4.0), but should specifically state in the cover memo that research involves "no more than minimal risk" and that expedited review is requested.

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C. Full Review: Research Involving More Than Minimal Risk to Human Subjects. Research in this category shall be reviewed by the IRB according to the procedures set out in Sections 5.0 through 8.0. Researchers should submit complete documentation of their research proposals as described in Sections 3.0 and 4.0.

2.2 Human Subject research conducted and/or sponsored by the University includes that conducted and/or sponsored by University employees, emeriti faculty, auxiliary employees, and/or students including student/faculty collaborative research under the auspices of the University.

A. For purposes of clarifying the researcher's legal rights and responsibilities, research or related activities conducted under the auspices of the University are defined to be any research or related activity involving human subjects that utilize Lesley University's time, facilities, resources, and/or students.

B. Lesley University affiliated investigators are afforded the normal legal protection by the University, provided that their activities have IRB approval and provided that they are working within the scope of their employment or University association. It is important to recognize that unless these conditions have been met, the University will not be in a position to protect Lesley University-affiliated investigators performing research with human subjects.

2.3 Extramural Support

Research requesting extramural support and planning to perform activities involving human subjects under the auspices of the University are required to submit an application for funds through the IRB. All extramural support requests should be submitted to the IRB a reasonable time in advance of deadline, receipt or submission dates specified by the operating agencies. Completed IRB review can, under no circumstances, be expected in less than 15 working days from receipt of a correctly completed application.

2.4 Student/Faculty Collaborative Research

Collaborative Research (student/faculty), where the faculty member is considered the principal investigator, must be submitted through the channels described below under Section 3.0, "Application Procedures."

2.5 Student Research Activities

Students conducting research involving human subjects must first submit a statement of research and research methodology to the department in which the research will be conducted.

2.6 The sponsoring faculty member forwards the protocol to the IRB.

2.7 Researchers are entitled to a timely review of research proposals. The IRB will *normally* complete its review within 15 working days of the submission of a complete, properly formatted proposal. In the event that the agenda of the IRB is full, and the IRB is unable to complete review of proposals within 15 working days, the researchers shall be informed properly. Upon request from researchers, the agenda of the IRB shall be reviewed to prioritize proposals by urgency for starting the research. In the case of expedited review, working days will normally be

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calculated based on days the campus is open. In cases of full review, only faculty work days in regular sessions are counted.

3.0 APPLICATION PROCEDURES

3.1 Researchers are required to submit a protocol describing the research or activity to the IRB. The chair and (depending on the nature of the research) the Board then reviews the protocol and takes action regarding approval.

3.2 All procedures related to the preparation of appropriate protocols as well as processes leading to their submission to the IRB are the responsibility of the University departments and researchers.

3.3 The IRB requires an application form and any other relevant documents such as surveys, questionnaires and consent forms. IRB review should be completed no later than 30, but not less than 15, working days from the submission of a complete, properly formatted application.

A. The **Application Form** should include the duration of research. If the research extends beyond one year, it is subject to annual review by the IRB. A sample of the form is available from the IRB website.

B. The application is a description of the research and an explanation of how the research complies with institutional policies regarding human subjects, and contains the information described below.

1. *Abstract*: This section should state the relation of the proposed research to previous scientific investigations in the field including relevant laboratory and animals studies. Clear justification for the participation of human subjects at this stage of the investigation must be given. Researchers should keep in mind that most members of the IRB are not experts in the research being reviewed. Adequate lay language explanations should be provided to allow the members of the IRB to understand the objectives, the methods, and the research implications, as well as the conditions and risks to which human subjects will be exposed.

2. *Methodology*: A detailed description of all procedures to be performed on human subjects for the purposes of research must be included. Observational or interview subjects for the purposes of research must be included. Observational or interview studies should indicate the type of contacts and interactions with subject and the means of observation to be used. **WHEN QUESTIONNAIRES ARE TO BE ADMINISTERED, A COPY SHOULD BE INCLUDED.** Standard psychological tests should be identified. Special attention will be given to issues of confidentiality in behavioral studies. In cases where information provided to subjects regarding procedures and purposes of the study would invalidate the objectives, the investigator procedures and purposes of the study would invalidate the objectives, the investigator should report to the IRB specific reasons for not informing subjects of the procedures. Devices or activities that are not customarily encountered by the subjects in their daily living or unusual applications of such devices or activities must be described in detail.

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Any special procedures involving unusual electrical devices, radioisotopes, or investigational new drugs (IND's) must also be described. Approval from appropriate campus or federal agencies must be obtained before IRB approval can be granted. Unusual electric devices must have Occupational Health and Safety approval. Radioisotopes or research involving any source of radiation must be first approved by the Environmental Health and Occupational Safety Committee, and "new" drug use must be first approved by the Federal Drug Administration.

A tentative time schedule for the various procedures--or flow-chart where appropriate--should be provided showing how long each aspect of the study will take, the frequency and timing of ancillary procedures, the nature and duration of human discomfort, and the precise location in which the study is to be conducted. Frequency, duration, and location of interviews or observations should be indicated in behavioral or social science studies.

Identify all personnel who will participate in or assist in the conduct of this research. Identify each individual by name, title and responsibility in this research project. Briefly outline each individual's qualifications. For procedures requiring special skills on the part of the investigators, licenses, accreditation, and/or background of the investigators that qualify them for performance of those procedures should be indicated.

3. *Participants*: Effects of sample size on the magnitude of risk and problems of risk management will be considered by the IRB.

Justification must be provided for the use of subject groups that are members of a population whose capability of providing informed consent is or may be absent or limited. These include children, persons with diminished mental capacity, the senile who are confined to institutions (whether by voluntary or involuntary commitment), and the unborn child or fetus. A pregnant woman's ability to provide consent is limited insofar as she and the unborn child can participate only in activities where: (1) the purpose is to meet the health needs of the mother, and the fetus will be placed at risk only to minimum extent to meet such needs; or (2) the risk to the fetus is minimal.

A detailed and specific discussion of potential problems involving the subject groups must be given.

4. *Potential Risks*: A discussion of the risks (see Section 18.0 for definitions), if any, to the subject is required. Such deleterious effects may be physical, psychological or social. Some research involves neither risk nor discomfort, but rather violations of normal expectations. Such violations, if any, should be specified.

A discussion of the management of risk is required. Procedures for protecting against or minimizing potential risks should be described (including confidentiality safeguards). An assessment of their likely effectiveness should be discussed. Management of risk procedures ranges from those applicable to a group (such as the exclusion of pregnant or potentially pregnant women from a study involving a new drug) to those applicable to an individual subject. (The IRB provides researchers with procedures for management of potential risk.)

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5. *Potential Benefits*: This section must provide a justification for the proposed study. The discussion should focus on the significance of the new knowledge that is being sought and an evaluation of the benefits to individuals and/or society with respects to the risks involved in the study.

6. *Confidentiality and Anonymity*: The researcher will describe how the identity of participants and their confidential information will be protected, including but not limited to:

- a. The separation of informed consent documents and research results such as completed surveys or data gathered.
- b. The assignment of identifiers designed to protect participant anonymity; this does not suggest, however, that anonymity is required. If participants' anonymity is not maintained then the researcher must describe why, specifically, participants will not remain anonymous.
- c. The protection of confidentiality in publications;
- d. The disposition of research materials and informed consent documents.

7. *Other*: The IRB relies on the expertise of the researchers to provide insight about any peripheral benefits or potentially harmful effects of the conduct of the research. Based on your past experience and knowledge, please identify any extraordinary moral, legal, or ethical concerns, either beneficial or harmful, which may have been linked to this type of research.

4.0 DOCUMENTATION OF INFORMED CONSENT

A. Except as provided in item C. of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. **A COPY SHALL BE GIVEN TO THE PERSON SIGNING THE FORM.**

B. Except as provided in item C. of this section, the consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent (see Section 4.1). This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

2. A short form written consent document stating that the elements of informed consent (see Section 4.1) have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. The witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

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C. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether he/she wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

D. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

E. If subjects are to be compensated, the nature of the compensation and its influence on subject participation must be discussed. Experimental subjects may be reasonably reimbursed for their participation in an experiment. Compensation to subjects should never constitute an undue inducement or coercion.

4.1 *The Consent Form*: The researcher conducting a project that might place any individual at risk is obligated to obtain and document legally effective informed consent. Informed consent means the knowing consent of an individual of his/her legally authorized representative so situated as to be able to exercise choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. (The IRB website provides a sample consent form.)

4.2 *Requirements for Informed Consent*: Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representation is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

A. *Basic elements of informed consent*. Except as provided in item C. or item D. of this section when seeking informed consent, the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

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2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and,
8. A statement that participation is voluntary; refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

B. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedures may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.

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C. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement of obtain informed consent provided the IRB finds and documents that:

1. The research of demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - a. Public benefit of service programs;
 - b. Procedures for obtaining benefits or services under those programs;
 - c. Possible changes in or alternatives to those programs or procedures;
 - or
 - d. Possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alternation.

D. The IRB may approve a consent procedure which does not include, or which alters, some or all the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

E. The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

F. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care to the extent which the physician is permitted to do so under applicable federal, state, or local law.

5.0 REVIEW OF THE APPLICATION BY THE IRB

5.1 Human subjects research that qualifies under the classification "involving no more than minimal risk" may be reviewed according to the procedures of expedited review. Expedited review procedures apply to certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

A. The IRB may use the expedited review procedure to review either or both of the following:

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1. Some or all of the research appearing on the list of eligible categories established by the Secretary of the U.S. Department of Health and Human Services and found by the reviewer(s) to involve no more than minimal risk.
2. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

B. 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. A research activity may be disapproved only after review in accordance with the non-expedited procedure.

C. The IRB shall adopt a method for keeping all members advised of research proposals that have been approved under the expedited review procedure.

D. The appropriate federal department or agency head may restrict, suspend, terminate, or choose not to authorize the use of the expedited review procedure by this institution or the IRB.

5.2 All other research proposals are submitted to the Associate Provost for incorporation into the agenda of the next IRB meeting for discussion by the entire membership or quorum of the IRB. A quorum, which is defined as the majority of the total membership (one half the members plus one), must be present before the IRB can be convened.

5.3 The review performed by the IRB will determine whether the subjects will be placed at risk.

A. The policy criterion for determining risk is defined as: "Subject at risk" means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods which are necessary to meet his/her needs or which increase the ordinary risks of everyday life, including the recognized risks inhered in a chosen occupation or field of service.

B. If risk is involved, the answers to the following three questions will be weighted:

1. Are the risks to the subject so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks?
2. Are the rights and welfare of any such subjects adequately protected?
3. Is legally effective informed consent obtained by adequate and appropriate methods in accordance with the provisions of the *Uniform Federal Policy for the Protection of Human Subjects*?

5.4 Researchers are encouraged to submit proposals for IRB review during the fall and spring semesters or the winter term; also, research proposals are accepted in the summer. Proposals

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submitted in the summer will be evaluated in the same way and under the same timeline as during the academic year.

6.0 ACTIONS BY THE IRB

6.1 IRB Review of Research

- A. The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
- B. The IRB shall require that certain information be given to subjects as part of informed consent.
- C. The IRB shall require documentation of informed consent or may waive the need for such documentation.
- D. The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- E. The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once a year, and shall have authority to observe or have a third party observe the consent process and the research.

6.2 IRB Actions

The IRB, after review and discussion of the protocol and application, may take one of four actions.

- A. Approve the research
- B. Require modification
- C. Disapprove the research
- D. Suspend or terminate research

6.3 IRB Approval of Research

- A. In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:
 - 1. Risks to subjects are minimized:
 - a. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and
 - b. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
 - 2. Risks to the subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be

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expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subject would receive even if not participating in the research). The IRB should not consider possible long-term effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy as among those research risks that fall within the purview of its responsibility).

3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purpose of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject of the subject's legally authorized representative.

5. Informed consent will be appropriately documented.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

B. When some or all the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

C. The research may involve some risk to the subjects. In such cases the IRB may find that this risk is not unreasonable, that the potential benefits outweigh the risks, and that risk management procedures have been taken to minimize risks.

6.4 IRB Requirement for Modification of Research

This action involves modifications, major or minor, to some part of the proposed study.

A. The IRB may require major modifications. This occurs when the IRB feels that it has insufficient information to take action, or when it feels that the research design contains significant risks and should be revised to minimize those risks to human subjects. The IRB may request that the investigator discuss problems with the full IRB directly or through a selected number.

B. Minor modifications or conditions set by the IRB include such items as revisiting the consent form to explain the procedures more clearly, adding a version of a consent form in a language other than English, restrictions on the use of certain procedures or subject

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groups or requiring use of specified safeguards, etc. that are necessary for the protection of human subjects. The IRB may request the investigator to discuss problems with the full IRB directly or through a selected member.

C. Modified research protocols must be resubmitted for approval. The IRB may choose to expedite review (see Section 5.0) for resubmissions involving minor modifications.

6.5 IRB Disapproval of the Research

In case of disapproval of the research, the IRB makes the decision that the potential benefits of the research do not outweigh the risks to the subject.

6.6 IRB Suspension or Termination of Approval of Research

The IRB has authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, the University President or designee, and the appropriate federal department or agency head.

7.0 DISPOSITION OF THE RECOMMENDATIONS

7.1 Approvals, recommendations, restrictions, conditions, or disapprovals are communicated to the researcher through the IRB. At the time of transmittal of approval, the IRB will also inform the researcher of the expiration date of approval.

7.2 If an application is not approved as conforming to Federal and University policies, the IRB shall forward to the researcher a statement setting forth in detail the reasons for the nonconformity and the recommendations of the IRB for modification of the research proposal.

A. Compliance with recommendations is expected within 3 working days of request if noncompliance is attributable to an incomplete application, e.g., one of the following reasons: lack of consent, assent, or similar form; missing or incomplete questionnaire(s), surveys, scripts, or similar such forms; an incomplete application for one of the aforementioned reasons or for any other reason(s), for example, failure to adequately address any component of the application.

1. The researcher will be notified of noncompliance by three methods: 1) phone call; 2) email; and 3) formal, written letter. If the researcher wants to pursue the noncompliant research after 3 working days of noncompliance, then a new IRB application will have to be submitted.

2. During the period of noncompliance no additional IRB applications will be accepted from the researcher or student research supervised by the researcher in noncompliance.

B. If noncompliance is for reasons other than an incomplete application, for example potential risk has not been adequately minimized, deception has not been adequately addressed, or some other sampling or methodological concern, the researcher is expected to address the concerns in writing to the IRB within 5 working days.

1. The researcher will be notified of noncompliance by three methods: 1) phone call; 2) email; and 3) formal, written letter. If the researcher wants to pursue the

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noncompliant research after the 5 working days of noncompliance, then a new application will have to be submitted.

2. Considering the nature of this noncompliance additional IRB applications may be submitted during the noncompliance period.

8.0 RIGHTS OF APPEAL

8.1 If the applicant believes that a proposal has been disapproved because of incorrect, unfair, or improper evaluation by the IRB, he/she may notify the University Provost or designee, who shall direct a reconsideration of the proposal by the IRB. Reconsideration of adverse final decisions on specific projects can be requested by the affected researcher(s) and/or department(s). The researcher may provide expanded information and explanation to the IRB. The reconsideration shall take place and a decision shall be reached within 15 working days of the IRB after the initial negative decision. The researcher and the University Provost or designee shall be notified of the results of the reconsideration immediately by the IRB.

A. At any point in the entire appeals process, the researcher may modify objectionable items to conform to IRB policy.

8.2 If satisfactory resolution has not been reached as a result of the reconsideration, the following appeals procedure will be used:

A. Within 15 working days of the IRB thereafter, the affected researcher(s) must show cause, to the University President or designee, in writing, as to why the IRB should reverse the decision.

1. An appeals committee of three (or more) tenured faculty (from at least two of the schools or colleges) will be appointed by the University President or designee to conduct a special appeals review. A member of the IRB may be added to the special appeals review committee to provide technical knowledge or other appropriate information. At the request of the researcher, an outside reviewer may be added to the appeals committee. The outside reviewer will usually be a member of the IRB of another institution.

2. The appeals committee shall:

- a. Review the initial proposal and reconsideration materials, submitted by researchers;
- b. Review relevant minutes of the IRB;
- c. Review IRB members' confidential evaluation forms; and,
- d. Request any expertise necessary for their deliberations.

3. The researcher may request an appearance before the IRB and/or the special appeals committee through the Office of Sponsored Projects or the IRB chair.

4. The special appeals committee may render one of the following recommendations:

- a. Return the proposal to the IRB for further reconsideration.
- b. Affirm the original decision of the IRB denying approval to the appealing researcher and/or department.

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5. The University President, having received the information from the IRB and the special appeals committee, shall make the final decision.

9.0 RECORDS AND DOCUMENTATION

9.1 Researcher

A. The investigator(s) is required to make and keep written records of the IRB reviews and decisions on the use of human subjects and to obtain and keep documentary evidence of informed consent of the subjects or their legally authorized representative. Such forms must be retained on file by the responsible individual for a minimum of five years after termination of the project.

B. Researchers will maintain records of research data.

C. Researchers will monitor the duration of their research to assure that a renewal application is submitted if research will continue beyond its initial anticipated duration and/or if it will continue beyond one year.

D. The researchers must periodically review research results to assure that: 1) unanticipated harm has not occurred; and 2) the research protocol is producing adequate results such that benefits of the research continue to balance risks to human subjects. If unanticipated harm occurs or results are inadequate to assure a balance of risks and benefit, the researcher must report immediately to the IRB.

9.2 IRB

A. The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any that accompany the proposals approved, sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
2. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in disapproved research proposals; and a written summary of the discussion of controversial issues and their resolution.
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the investigators.
5. A list of IRB members.
6. Written procedures for the IRB.
7. Statements of significant new findings provided to subjects.

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B. The records required by this policy shall be retained for at least three years, and records relating to research that is conducted shall be retained for at least three years after completion of the research. The records of the IRB pertaining to individual research activities will not be accessible outside the IRB and the individual researcher, except for the purposes of audit or inspection by federal agencies to assure compliance.

9.3 Institution- Lesley University

It is the responsibility of Lesley University through the IRB to assure compliance with and provide documentation of compliance with the *Uniform Federal Policy for the Protection of Human Subjects*.

A. Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy:

1. Whenever research is engaged which is covered by this policy and supported by a federal department or agency, written assurance of compliance shall be submitted to the department or agency head or kept on file within the Office for Human Research Protection, U.S. Department of Health and Human Services, 200 Independence Ave. S.W., Washington, D.C., 20201. Any report to federal department or agency heads required by this policy shall also be submitted to the Office for Human Research Protection if an assurance has been filed there.

2. In lieu of requiring separate submission of an assurance, individual federal department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protection, HHS and approved for federal wide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protection, HHS.

B. Federal departments and agencies will support research covered by this policy only if Lesley University has an assurance approved as provided in this section, and only if Lesley University has certified to the department or agency head that the research has been reviewed and approved by the IR provide for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

1. The Lesley University statement of principles governing the discharge of its responsibilities for protecting the rights and welfare of human subjects in research conducted at or sponsored by Lesley University, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institutional itself. This requirement does not preempt provisions of this policy applicable to department or agency-supported or regulated research. The requirement need not be applicable to research classified as exempt or specific research activities or classes of research for

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which, unless otherwise required by law, federal department or agency heads have waived the applicability of some or all provisions of this policy.

2. Designation of the IRB established in accordance with the requirements of this policy and with provisions made for meeting space and for sufficient staff to support the IRB's review and record-keeping duties.

3. A list of IRB members identified by name, earned degrees, representative capacity, indications of experience (such as board certifications, licenses, etc. sufficient to describe each member's chief anticipated contributions to IRB membership) shall be reported to the department or agency head, unless the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, HHS.

4. Written procedures which the IRB will follow, as embodied in this policy:

a. For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

b. For determining which projects require review more than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and

c. For ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

5. Written procedures for ensuring prompt reporting to the IRB, the University President or designee, and the federal department or agency head of:

a. Any unanticipated problems involving risks to subjects or other or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and

b. Any suspension or termination of IRB approval.

c. The assurance shall be executed by the University President or designee who is authorized to act for the institution and to assume, on behalf of Lesley University, the obligations imposed by this policy and shall be filed in such form and manner as the federal department or agency head prescribes.

9.4 Federal Departments and Agencies

A. The federal department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or

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agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

B. On the basis of this evaluation, the federal department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

C. Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived. An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by this policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

10.0 DURATION OF APPROVAL

10.1 The IRB shall conduct at least an annual review of approved research activities. Researchers should indicate the expected overall duration of the research when submitting an initial application. Renewal applications should be made before the date of expiration of IRB approval, bearing in mind the time needed for review and that research activity must cease at expiration date if renewal has not been obtained.

10.2 The IRB will determine the term of approval and will notify the researcher of the date of expiration of approval at the date of approval.

10.3 Approval of a protocol is granted to the principal investigator. If the principal investigator ceases to be responsible for the study, approval automatically ceases. Should a new principal investigator desire to continue the study, reapplication (see 11.0 below) to the IRB is required.

11.0 RENEWAL APPLICATIONS AND MODIFICATIONS OF PROTOCOLS

11.1 Renewal of approved protocols is required annually and is also required if the principal investigator changes. If during the course of any research, training, or demonstration a change in plans is made so that human subjects are now to be used, or that the research methods or techniques are significantly different, or new hazards are evident, a statement of such change in

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plans must be submitted to the IRB and an approval of modification of the existing protocol must be obtained. In general, any change which alters the risk/benefit balance or which modifies the informed consent in some way requires approval.

11.2 Renewal Applications

Renewal applications require:

- A. A copy of the current or new consent form.
- B. A copy of the previously approved protocol.
- C. A status report which provides a brief discussion of the work accomplished to date, including particularly:
 1. The number of subjects studied (and the number approached who refused permission).
 2. A discussion of the experience of the subjects undergoing study, with particular reference to any adverse events occurring to them during the conduct of the study. Note that if no adverse events have occurred, it should be stated, rather than omitting this item altogether.
 3. A brief description of the scientific or research results, if any, to date.

11.3 Modification Applications

A. Modification applications require:

1. A copy of the current or new consent form.
2. A copy of the previously approved protocol.
3. A description of any modifications to the current or previous protocol which are desired. For these, the description and justification should proceed much as outlined for a new application; that is, the background or reason for modification, benefits, risks, etc. When responsible positions are assumed by new personnel in the execution of the protocol (such as change of the principal investigator), a description of the background of the individuals with regard to the work described in the protocol (as in the original application) should be given.

B. Progress reports should not be photocopies of papers (either published or submitted for publication). The papers primarily inform their readership of scientific advances. It is necessary to inform the IRB, in as concise a manner as possible, of the results as they influence the balance of benefit to risk to human subject. Published papers may be appended as evidence of benefits of the research.

12.0 UNANTICIPATED PROBLEMS

Any unanticipated problems involving risk to subjects or others, including adverse reactions to biologicals, drugs, radioisotope labeled drugs, or to medical devices must be reported

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immediately to the IRB and to any federal agency sponsoring the project by the researcher. Reports should include:

- A. Identification of individual(s) involved.
- B. Identification of principal investigator, title of project and project number.
- C. A description of adverse reactions and any possible association with the experimental procedures, drugs, medical devices, etc.
- D. Any relevant information on the subject (previous exposure to drugs, therapy, case history, background information, etc).

13.0 VIOLATIONS OF THESE POLICIES AND PROCEDURES

13.1 Noncompliance with these policies and procedures is subject to disciplinary action and possible litigation. Violations of these policies and procedures should be reported to the IRB immediately.

13.2 The IRB will review allegations of these policies and procedures, and will follow the policies and procedures as set forth in the Lesley University Policy on Maintenance of Integrity in Research, and other regulations governing faculty, staff, and student ethical conduct as appropriate.

13.3 If any research which is federally funded is found to be in violation of any of the federally-mandated portions of this policy, or of appropriate federal regulations regarding the protection of human subjects, the IRB shall report such to the University Provost or designee, who in turn shall report same to the appropriate agency on behalf of the researcher, if the researcher fails to report.

13.4 Violations will follow the disciplinary procedures outlined in the most current collective bargaining contract and/or Title V regulations, as appropriate.

14.0 ADVICE AND CONSULTATION TO RESEARCHERS AND DEPARTMENTS

14.1 Researchers and departments may call the IRB for informational consultation. This panel will consist of current and previous members of the IRB in addition to other individuals approved by the IRB.

14.2 Any consultation extended is informational in nature; it is neither interpretative nor decisional as these are the prerogatives of the IRB in its review function.

15.0 OMISSIONS

In the event that issues related to the use of human subjects in research at Lesley University are not covered by this policy, the IRB will rely on the *Uniform Federal Policy for the Protection of Human Subjects*.

16.0 AMENDMENTS

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16.1 This policy shall be amended when necessary by two-thirds vote of the membership of the IRB.

16.2 Should major revision of this policy become necessary, the Academic Deans and the All College Committee will be consulted to provide advice to the Provost/Vice President for Academic Affairs.

16.3 The final authority for amendment of these policies and procedures and for the adoption of a new revision rests with the University President.

17.0 MEMBERSHIP AND APPOINTMENT OF IRB

A. The IRB shall be comprised of no fewer than seven members.

B. The membership of the IRB shall include:

1. Associate Provost who serves as Director.
2. At least one faculty member from each college or school of the University, chosen to assure representation by both scientific and nonscientific personnel.
3. At least one person qualified to assess each of the following risks: physical (medical), psychological, social.
4. At least one person qualified to assess the validity of experimental design so the benefits of the research may be adequately addressed.
5. At least one member from the community at large not otherwise affiliated with Lesley University.
6. Additional members as necessary to provide special expertise for adequate attention to the risks of certain research subject populations.

C. Membership shall include a balanced representation of ethnicity and gender.

D. New members will be selected by the Chair of the IRB in consultation with past and present members of the IRB, university or school deans and appropriate vice presidents. Members shall be appointed by the University Provost or designee to serve overlapping five-year terms.

E. The All College Committee will be informed of any changes in IRB membership.

18.0 DEFINITIONS

18.1 Certification (Uniform Federal Policy definition)

Certification means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that research project of activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

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18.2 Cooperative Research (Uniform Federal Policy definition)

Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

18.3 Human Subject (Uniform Federal Policy definition)

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- A. Data through intervention or interaction with the individual; or
- B. Identifiable private personal information.

18.4 IRB (Uniform Federal Policy definition)

IRB means an institutional review board established in accordance with and for the purposes expressed in this policy.

18.5 IRB Approval (Uniform Federal Policy definition)

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

18.6 Minimal Risk (Uniform Federal Policy definition)

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.

18.7 Physical Risk

Physical risks include any potential for physical injury or deleterious effects to subject's health, either short term or long term.

18.8 Psychological Risk

Psychological risk refers to the impact of research that interrupts the normal activity of human subjects resulting in immediate and/or long-term stress that would not otherwise be experienced by the individual.

- A. Stress involves any situation that poses a threat to desired goals or homeostatic organismic conditions and thus places strong adaptive demands on the individual.
- B. Stress can be experienced during the actual experimental situation (immediate) and/or as a result of participation in the experiment (long term).
- C. Some examples of situations that may result in stress are:
 - 1. Undue coercion

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2. Exposure to noxious events
3. Request or demand for behaviors that are discrepant with individuals, values, morals, and/or ethics.
4. The requirement of excess physical effort.

18.9 Research (Uniform Federal Policy definition)

Research means 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 that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

18.10 Social Risk to Groups

Social risk to groups is the extent to which a subject formal or informal group, as a collective, is exposed to loss with respect to factors affecting the viability and vitality of the group. Such loss includes (but is not limited to) derogatory labeling, overt hostile reactions from the social environment, reduced access to resources, diminished ability to recruit and retrain members, negative effects on morale and other aspects of internal cohesion and organization, violation of legally required procedures or risk of damage claims through civil action where there is corporate liability, reduced opportunities for communication, distortion of group activities relative to established group purposes and functions.

18.11 Social Risk to Individuals

Social risk to individuals is the extent to which an individual subject is exposed to deprivation with respect to desired relationships with and within both formal and informal social groups, or normal opportunities for such relationships. Such deprivations include (but are not limited to) derogatory labeling, overt hostile reactions by others, diminished access to otherwise available roles, negative effects on social standing or mobility, reduced opportunity for communication, lost or endangered membership in such groups.

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VII. INSTITUTIONAL ANIMAL CARE AND USE

In compliance with the National Institutes for Health (NIH) "Guide for the Care and Use of Laboratory Animals" For conducting Institutional Animal Care and Use Committee (IACUC) Semi-annual program evaluations

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INTRODUCTION

Purpose

Humane care, use, and treatment of animals for instructional, research-related purposes are institutional responsibilities. The Lesley University Institutional Animal Care and Use Committee (IACUC) will consist of no fewer than five persons appointed by the Provost. The IACUC will provide the following:

- 1) Oversight and evaluation of the University's animal program, procedures, and facilities to ensure they are consistent with the recommendations of cited references shown at the end of this document.

- 2) Timely certifications and reports on the humane care and use of animals as required by governmental agencies.

Applicability

This Policy is applicable to all activities involving animals, whether the activities are performed at LU, at collaborating institution(s), or in the field. Investigators conducting activities involving animals shall comply with this Policy which sets forth standards for the humane care and use of animals.

This Policy follows applicable state and local laws or regulations which impose more stringent standards for the care and use of laboratory animals, and includes the *Animal Welfare Act* and other Federal statutes and regulations relating to animals.

Responsibilities and Procedures

- a. The University IACUC shall maintain records of committee activities. These records shall be available for inspection by authorized representatives of governmental agencies.

- b. Deans, Chairpersons, or faculty members having jurisdiction over animal care and use facilities are responsible for the implementation of professionally acceptable standards for the care and use of all animals within their jurisdiction and assuring that those standards are met.

- c. All investigators, including students, must follow the procedures and guidelines set forth by the IACUC and additionally accept responsibility to assure actions dealing with animals will be in accordance with humane standards and the laws and regulations cited below in the section, Definitions and References. Investigators are responsible for authorized care and use of animals by students under their supervision.

- d. Standards for the construction and use of housing, service, and surgical facilities for animals shall meet those described in the *Guide* of otherwise required by the Animal Welfare Act (P.L. 89-544).

- e. Transportation of animals must be in accord with state and applicable standards and promptly delivered, uncrated, and placed in the Animal Care facility.

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- f. Acquisition of animals shall be in accordance with state and federal laws and regulations.
- g. Disposal of dead animals shall be in accordance with governmental regulations.
- h. All activities involving animals for which the University bears any responsibility must be considered by the University IACUC in accordance with protocol review procedures.

Definitions

- a. *Animal*- Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.
- b. *Animal Facility*- Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.
- c. *Animal Welfare Act*- Public Law 89-544, 1966, as amended, (P.L. 91-579, P.L. 94-279 and P.L. 99-198) 7 U.S.C. 2131 et. seq. Implementing regulations are published in the *Code of Federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Parts 1, 2 and 3*, and are administered by the U.S. Department of Agriculture.
- d. *Animal Welfare Assurance or Assurance*- The documentation from an institution assuring institutional compliance with this Policy.
- e. *Guide*- Guide for the Care and Use of Laboratory Animals. National Academy Press, 1996, Washington D.C., or succeeding revised editions.
- f. *Institution*- Any public or private organization, business, or agency (including components of Federal, state, and local government).
- g. *Institutional Official*- An individual who signs, and has the authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirements of the Policy will be met.
- h. *Public Health Service*- The Public Health Service or PHS currently includes the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.
- i. *Quorum*- A majority of the members of the Institutional Animal Care and Use Committee (IACUC).

INSTITUTIONAL POLICIES

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1. Monitoring the Care and Use of Animals- the IACUC

a. The University IACUC will provide: 1) oversight and review of all animal care and use facilities and procedures; and 2) timely certifications and reports of the humane care and use of animals as required by governmental agencies.

b. The University IACUC will consist of no fewer than five persons appointed by the President as described in the Guide.

c. The meetings of the IACUC shall be held at least twice per year. These meetings will usually be held once during the Fall Semester and once during the Spring Semester. The minutes of the meetings and memoranda to the General Faculty will serve as documentation of compliance.

d. Campus personnel (faculty, staff, or students) wishing to conduct animal research or procedures shall complete the appropriate documents and submit them to the Office of Sponsored Projects, which shall forward the materials to the IACUC. Guidelines and forms are available in the Office of Sponsored Projects

e. Project proposals shall be submitted for approval to the IACUC and shall include complete descriptions for use of animal subjects. Intramural activities submitted for approval shall include a project description, scientific procedures, and budget (if applicable).

f. Project proposals shall provide the following information:

(a) The nature and objectives of the investigation to be performed on the animal subjects

(b) Species and number of animals to be used

(c) The rationale for use of the animals

(d) Proposed methods to avoid unnecessary discomfort and/or injury to the animals

(e) Location of facilities for care and use of animal subjects

(f) Requirements for care and use of the animal

g. The University IACUC will evaluate the application for the following:

(g) Adherence to provisions and standards of applicable laws and regulations and campus policies

(h) Provisions for humane care, handling, and use of animal subjects

(i) Appropriate use of anesthetic, analgesic, tranquilizing and euthanating agents

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- (j) Proper arrangement for animal care and use facilities
- (k) Agreement with the following principles:
 - (i) Procedures should be designed to yield useful results and should be based on knowledge of the disease, problem, or biology of the animal under study
 - (ii) Procedures should avoid all unnecessary suffering and injury to animals. It is therefore essential that personnel caring for and using animals be very familiar with species-specific and individual behavioral, physiologic, and biochemical indicators of pain
 - (iii) Persons in charge of the procedures will be prepared to terminate the procedures whenever their continuation may result in unnecessary injury or suffering to the animals.
 - (iv) If a procedure is likely to cause greater discomfort than anesthetization, the animal must first be rendered incapable of perceiving pain and be maintained in that condition until the procedure is ended.
 - (v) Post experimental care of animals must be such as to minimize discomfort in accordance with acceptable practices in veterinary medicine.
 - (vi) Animals that are sacrificed must be treated humanely and in such a way as to ensure rapid and painless death. No animal shall be discarded until after it is dead. Attempts to donate surplus animals to other institutions or individuals for humane purposes should be made as an alternative to destruction and must be approved by the IACUC and those who receive animals must first sign a statement assuming responsibility for the animals received.

Veterinary Care

- a. A doctor of veterinarian medicine will visit and inspect the animals and facilities twice per year, or once every six months where animals are held for 24 hours or more.
- b. Adequate veterinary care consists of observing all animals daily, if required, to access their health and welfare; using appropriate methods to prevent, control, diagnose, and treat diseases and injuries; providing guidance to users regarding handling, and immobilization, anesthesia, analgesia, and euthanasia; and monitoring surgery programs and post surgical care.
- c. Veterinary care is the responsibility of a veterinarian who is certified or has training or experience in the laboratory animal science and medicine. Observation of animals can be accomplished by someone other than a veterinarian; however, a mechanism of direct

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and frequent communication should be adopted so that timely and accurate information on problems in animal health, behavior, and well-being is conveyed to the attending veterinarian.

d. The veterinarian can also contribute to the establishment of appropriate policies and procedures for ancillary aspects of veterinary care, such as advising on experimental models; reviewing protocols and proposals with respect to veterinary care, animal husbandry, and animal welfare; monitoring occupational health, hazard containment, and zoonosis control programs; and supervising animal nutrition, husbandry, and sanitation.

Personnel Qualifications

a. A licensed, experienced veterinarian will serve as the animal resource professional.

b. Qualified personnel will oversee the day-to-day care of the animals.

c. The research staff is well qualified, experienced faculty members. When students are involved as researchers, they are supervised by these faculty members.

Occupational Health Program

a. Content of Program

An occupational health program is mandatory for personnel who work in laboratory animal facilities or have substantial animal contact. This program requires a physical examination and a medical and work history prior to beginning any work. Periodic physical examinations are advised as following occupational hazards such as animal bites or exposure to hazardous biological, chemical, and physical agents.

b. Program Oversight

The University IACUC will oversee the implementation of the Occupational Health & Safety Program in relation to the Animal Welfare Program.

c. Participation

An appropriate immunization schedule for all animal and investigative staff is followed, including immunization against tetanus and for people who handle animals at substantial risk of infection with such agents as rabies virus and hepatitis B virus.

d. Training on Zoonosis

Zoonosis surveillance is part of an occupational health program and includes keeping records of individual work assignments, bite wounds, and unusual illnesses (CDC, 1984; Fox et al., 1984). Personnel are instructed to notify their supervisors of illnesses and of suspected health hazards. Furthermore, consideration is given to illnesses and storing individual pre- and post-employment serum samples for future diagnostic purposes.

Non-human primate diseases that are transmissible to humans can be a serious hazard. Personnel (including animal technicians, clinicians, investigators, students, research technicians, and, maintenance workers, and security personnel) who are in

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contact with non-human primates are encouraged to undergo regularly scheduled tests for tuberculosis.

e. Personal Protective Equipment

Personal protective clothing, equipment and other safety measures prescribed by the ES&H policy must be utilized as often as necessary and should not be worn beyond the boundary of the hazardous-agent work area or the animal facility.

f. Personal Hygiene

A high standard of personal cleanliness is essential. Personnel are not permitted to eat, drink, use tobacco products, or apply cosmetics in animal rooms. Refer to ES&H with regard to laundering services, decontamination methods.

Experimentation involving Hazardous Agents

a. Policies and Procedures

Protective devices and other safety measures consistent with current practices are used to guard against exposure to potentially hazardous biological, chemical and physical agents (CFR, 1984a, b).

b. Monitoring

The University Public Safety Officer is knowledgeable about hazardous agents and is appointed to evaluate safety issues. The procedures and facilities used in such studies are reviewed by both this officer and the Animal Welfare Committee. Formal safety programs are established to assess the hazards, determine the safeguards needed for their control, and ensure that the staff is competent and the facilities are adequate for the safe conduct of the research. Technical support is provided to monitor compliance with federal, state, and local regulations and institutional biosafety policies.

c. Animal Restraint

Brief physical restraint of animals for examination, collection of samples, and a variety of other clinical and experimental manipulations can be accomplished manually or by mechanical means. Such devices must be suitable in size and design for the animal being held and must be operated properly to minimize discomfort and to avoid injury to the animal.

Prolonged restraint of any animal, including the chairing of non-human primates, is avoided unless essential to research objectives. Less restrictive systems, such as the tether system should be used when compatible with research objectives. Additional guidelines are included in the Guide for the Care and Use of Laboratory Animals, 1996.

Multiple Major Surgery Procedures

Multiple major survival surgical procedures on a single animal are discouraged. However, under special circumstances they might be permitted with the approval of the IACUC. One situation in which multiple survival surgical procedures might be justified when they are related components of a research project. Cost savings alone is not an adequate reasons for performing multiple survival surgical procedures.

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LABORATORY ANIMAL HUSBANDRY

1. Food

Animals should be fed palatable, non-contaminated, and nutritionally adequate food daily or according to their particular requirements unless the protocol in which they are being used requires otherwise (*Guide for the Care and Use of Laboratory Animals, 1996*). The PI will define in his/her proposal to the IACUC a full description of food-related protocols.

2. Water

Animals should have access to potable, uncontaminated drinking water according to their particular requirements. The PI will define in his/her proposal to the IACUC a full description of water-related protocols.

3. Housing

Animal housing will be appropriate to the animal and comply with relevant regulatory guidelines. The investigator will identify applicable guidelines and describe how animal facility housing complies. The caging or housing system is designed carefully to facilitate animal well-being, meet research requirements, and minimize experimental variables.

The housing system provides adequate space that:

- permits freedom of movement and normal postural adjustment;
- has a resting place appropriate to the species;
- provides a comfortable environment;
- provides an escape-proof enclosure that confines animals safely;
- provides easy access to food and water;
- provides adequate ventilation;
- meets the biological needs of the animals, e.g., maintenance of body temperature, urination, defecation, and if appropriate, reproduction;
- keeps the animal dry and clean, consistent with species requirements;
- avoids unnecessary physical restraint; and
- protects the animals from known hazards.

Caging systems are constructed of sturdy, durable materials and designed to minimize cross-infection between adjoining units. Cages have smooth, impervious surfaces that neither attract nor retain dirt and a minimum of ledges, angles and corners in which dirt or water can accumulate. The design allows inspection of cage occupants without disturbing them. Feeding and watering devices are easily accessible for filling, changing, cleaning and servicing.

Cages, runs, and pens are kept in good repair to prevent injury to animals, promote physical comfort, and facilitate sanitation and servicing. Particular attention is given to eliminating sharp edges and broken wires, keeping care floors in good condition, and refurbishing or replacing rusted or other deteriorating equipment.

The social environment considers whether the animals are naturally territorial or communal and whether they will be housed singly or in groups. When appropriate, group housing is considered for communal animals. In grouping animals, population density and ability to disperse, initial

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familiarity among animals, and age, sex, and social rank are considered. Recommendations about space, temperature and humidity, ventilation, and illumination, and noise may be found in *Guide for the Care and Use of Laboratory Animals* are followed.

4. Bedding

The most suitable bedding will be determined by the veterinarian or facility manager, in consultation with the PI. The PI will define in his/her proposal to the IACUC a full description of bedding protocols.

5. Sanitation

Sanitation is the maintenance of conditions conducive to health and involves bedding change, cleaning, and disinfection. The frequency and intensity of cleaning and disinfection should depend on what is needed to provide a healthy environment for an animal. The PI will define in his/her proposal to the IACUC a full description of bedding protocols.

6. Behavioral Needs

According to the Animal Welfare Act captive animals have the freedom to express normal species typical behavior. For example, pigs are highly motivated to engage in rooting behavior and should therefore be provided with appropriate rooting substrate. The various types of environmental enrichment used with the captive lab animals will depend upon the individual species under study. The PI will define his/her enrichment program in their proposal to the IACUC.

7. Animal Identification and Records

Animal records allowing identification of animals, sources of acquisition, and methods of disposal will be maintained by the PI and made available to the IACUC upon request.

8. Provisions for Emergency, Weekend and Holiday Care

The PI will identify responsible personnel and feeding, cleaning, and care protocols for animals for any period of time during which the PI is unable to provide expected levels of care. The PI will define in his/her proposal to the IACUC provisions to be made for animal care during emergencies, weekends, and holidays.

VETERINARY CARE

1. Animal Procurement and Transportation

All animals must be acquired lawfully and purchased from reliable vendors. Vendors should be evaluated and approved based upon prescribed vendor selection criteria. Generally, vendors of purpose-bred animals regularly provide information that describes the genetic and pathogen status of their animals. This information is useful for deciding on acceptance or rejection of animals, and similar data should be obtained on animals received by inter-institutional or intra-institutional transfer.

All transportation of animals, including intra-institutional transportation, should be planned to minimize transit time and the risk of zoonoses, protect against environmental extremes, avoid overcrowding, provide food and water when indicated, and protect against physical trauma.

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Efforts must be made to minimize as much as possible transportation-related stress to the animal(s).

Each shipment of animals is inspected for compliance with procurement specifications, and the animals are quarantined and stabilized according to procedures appropriate for the species and circumstances.

2. Preventative Medicine

The veterinarian formulates standard operating procedures to evaluate the health status of newly received, quarantined animals in accordance with acceptance veterinary medical practice and federal, state and local regulations.

Quality control by the vendor and knowledge of the history of the animals are acceptable parts of an institution's quarantine protocol. This information may limit the quarantine period for rodents to the time necessary for inspection on arrival; however, all newly received animals should be allowed a stabilization period prior to their use. This permits animals to adapt to their surroundings, resulting in a more stable physiological and behavioral state. If the history of newly received animals is incomplete, the quarantine procedure is more comprehensive and of sufficient duration to allow expression of diseases, including zoonoses; physiological and nutritional stabilization; and grooming, including bathing, dipping and clipping as required.

Physical separation of animals by species is generally recommended to prevent interspecies disease transmission, reduce anxiety due to interspecies conflict, and meet experimental requirements. Intraspecies separation is advisable when animals obtained from multiple sources differ in microbiological status. (Additional guidelines are detailed in the *Guide for the Care and Use of Laboratory Animals*).

3. Surveillance, Diagnosis, Treatment and Control of Animal Diseases

Incoming animals are screened. All laboratory animals are observed daily for signs of illness, injury or abnormal behavior by a person trained to recognize such signs. Unexpected deaths and deviations from normal are reported promptly to the person responsible for animal disease control. Sick or injured animals receive prompt veterinary medical care or are euthanized appropriately. Animals that are suspected of having contagious disease are isolated from healthy animals in the colony. When an entire group or room of animals is known or believed to be exposed to an infectious agent, the group is kept intact during the process of diagnosis, treatment and control.

Methods of prophylaxis, therapy and disease control follow currently accepted practices. Diagnostic laboratory services supplement physical examination and facilitate diagnosis of diseases. These services include gross microscopic pathology, clinical pathology, hematology, microbiology, clinical chemistry, and other appropriate laboratory procedures. Inapparent viral infections of rodents, which can occur with mouse hepatitis virus, minute virus of mice and lactic dehydrogenase virus, can have an affect on some types of research.

4. Anesthesia and Analgesia

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The proper use of anesthetics, analgesics, and tranquilizers in laboratory animals is necessary for humane and scientific reasons. The choice and use of the most appropriate drugs are matters for the attending veterinarian's professional judgment. The veterinarian provides research personnel with guidelines and advice concerning choice and use of these drugs.

If a painful procedure must be conducted without the use of an anesthetic, analgesic, or tranquilizer - because such use would defeat the purpose of the experiment- the procedure must be approved by the University IACUC and supervised directly by the responsible investigator.

Muscle relaxants or paralytic drugs (e.g., succinylcholine or other curariform drugs) are not anesthetics. They are not used alone for surgical restraint, although they can be used in conjunction with drugs known to produce adequate analgesia.

5. Survival Surgery and Post Surgical Care

The following procedures apply to both non-rodent mammalian and rodent species:

A. Aseptic surgery is conducted only in facilities intended for that purpose. These facilities are maintained and operated to ensure cleanliness and directed and staffed by trained personnel. Surgery is performed or directly supervised by trained, experienced personnel. Training in aseptic surgery is provided for those who require it.

B. Aseptic technique is used on most animals including lagomorphs that undergo major survival surgery. This technique includes wearing of sterile surgical gloves, gowns, caps and facemasks; use of sterile instruments; and aseptic preparation of the surgical field. Major survival surgery is defined as any surgical intervention that penetrates a body cavity or has the potential for producing a permanent handicap in an animal that is expected to recover. Survival surgery on rodents does not require a special facility but should be performed using sterile instruments, surgical gloves, and aseptic procedures to prevent clinical infections.

C. Appropriate facilities and equipment are available for post surgical care. Post surgical care includes observing the animal to ensure uneventful recovery from anesthesia and surgery; administering supportive fluids, analgesics, and other drugs as required; providing adequate care for surgical incisions; and maintaining appropriate medical records. Equipment and supply items that can be helpful for intensive care include heating pads, vaporizers, vacuum equipment, respirator, cardiac monitor, and oxygen. Proper monitoring by trained personnel is provided during recovery.

D. Minor surgical procedures, such as wound suturing and peripheral vessel cannulation, is performed under less stringent conditions when they are performed in accordance with standard veterinary practices.

6. Euthanasia

Euthanasia, the procedure of killing animals rapidly and painlessly, is carried out by trained personnel using acceptable techniques in accordance with institutional policies and applicable laws. The method used should not interfere with postmortem evaluation. Techniques for euthanasia follow current guidelines established by the American Veterinary Medical

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Association Panel on Euthanasia (ACMA, 1978). Other methods must be reviewed and approved by the institutional veterinarian. Acceptable methods of euthanasia are those that initially depress the central nervous system to ensure insensitivity to pain (Canadian Council on Animal Care, 1980). For this reason, anesthetic agents are generally acceptable and animals of most species can be killed quickly and humanely by intravenous or intraperitoneal injection of an overdose of barbiturates. Other methods can be used for euthanasia of anesthetized animals because the major criterion of humane treatment has been fulfilled (Lucke, 1979). Every attempt is made to perform euthanasia on animals in a manner that minimizes reactions among other living animals. Proper euthanasia technique includes a follow-up examination to confirm the absence of a heartbeat, which is a reliable indicator of death. Monitoring respiration is not sufficient. In some animals, particularly under deep carbon dioxide anesthesia, heartbeat can be maintained after visible respiration has ceased, and the animal might eventually recover.

PHYSICAL PLANT

1. Arrangement and Condition of Facility

Animal facilities will be designed and constructed in accord with all applicable state and local building codes. Such facilities will be well-planned, well-designed, well-constructed based upon the scope of institution research activities the animals to be housed. Good animal management and human comfort and health protection require separation of animal facilities from personnel areas, such as offices, and conference rooms. Careful planning would make it possible to place animal housing areas next to or near research laboratories but separated from them by barriers, such as entry locks, corridors, or floors. Animals should be housed in facilities dedicated to or assigned for that purpose and not be housed in laboratories merely for convenience.

REFERENCES

1. General policies

- a. Animal Welfare Act as Amended (7 USC, 2131-2156)
- b. Guide for the Care and Use of Laboratory Animals, National Academy Press, 1996, Washington D.C., or succeeding revised editions.
- c. Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, Revised August, 2002.
- d. DHEW and PHS Grants Administration Manuals, Chapter 1-43 Animal Welfare, and any succeeding revisions.
- e. Applicable provisions and regulations of the Massachusetts Department of Public Health.
- f. Applicable provisions and regulations of the Marine Mammal Protection Act of 1972, P.L. 92-522, and any succeeding amendments.
- g. Applicable provisions and regulations of the Endangered Species Act of 1973, P.L. 93-205, and any succeeding amendments.

2. Occupational Health and Safety Policies

- h. Forthcoming from Patty Delaney

3. Environmental Health and Safety Policies

- a. Forthcoming from Patty Delaney
- b. Applicable publications containing these regulations and guidelines include:
 - (1) Code of Federal Regulations. 1984. Title 10; Part 20, *Standards for Protection Against Radiation*. Washington D.C.: Office of the Federal Register.

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- (2) Code of Federal Regulations. 1984. Title 29; Part 1910, *Occupational Safety and Health Standards*; Subpart G, *Occupational Health and Environmental Control*, and Subpart Z, *Toxic and Hazardous Substances*. Washington D.C.: Office of the Federal Register.
- (3) Code of Federal Regulations. 1984. Title 40; Part 260, *Hazardous Waste Management System: General*; Part 261, *Identification and Listing of Hazardous Waste*; Part 262, *Standards Applicable to Generators of Hazardous Waste*; Part 263, *Standards Applicable to Transporters of Hazardous Waste*; Part 264, *Standards for Owners and Operators of Hazardous Waste Treatment Storage, and Disposal Facilities*; Part 265, *Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage and Disposal Facilities*; and Part 270, *EPA Administered Permit Programs: The Hazardous Waste Permit Program*. Washington D.C.: Office of the Federal Register.
- (4) Centers for Disease Control and National Institutes of Health. 1984. *Biosafety in Microbiological and Biomedical Laboratories*. DHHS Pub. No. (CDC) 84-8395. *Involving Oncogenic Viruses*. DHEW Pub. No. (NIH) 78-790. Washington D.C.: U.S. Department of Health, Education and Welfare. 20 pp.
- (5) National Cancer Institute. 1976. *Biological Safety Manual for Research Involving Oncogenic Viruses*. DHEW Pub. No. (NIH) 76-1165. Washington D.C.: U.S. Department of Health, Education and Welfare.
- (6) National Institutes of Health. 1979. *Laboratory Safety Monograph. A Supplement to the NIH Guidelines for Recombinant DNA Research*. Washington D.C.: U.S. Department of Health Education, and Welfare, 227 pp.
- (7) National Institutes of Health. 1981. *NIH Guidelines for the Laboratory Use of Chemical Carcogens*, NIH Pub. No. 81-2385. Washington D.C.: U.S. Department of Health and Human Services.
- (8) National Institutes of Health. 1984. *Guidelines for Research Involving Recombinant DNA Molecules*. Federal Register 49(227): 46266-46291.
- (9) Subcommittee on Arbovirus Laboratory Safety, American Committee on Arthropod-Borne Viruses. 1980. *Laboratory safety for arboviruses and certain other viruses of vertebrates*. Am. J. Trop. Med. Hyg. 29:1359-1381.

4. Hazardous Agents Policies

- a. Forthcoming from Patty Delaney

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VIII. HAZARDOUS MATERIALS

PURPOSE

Lesley University is committed to protecting the health, safety, and welfare of faculty, staff, students, and the public and to protecting the environment through a comprehensive hazardous substances management program. The elimination of dangerous combinations of hazardous chemicals in storage, the elimination of hazardous accumulations of unwanted substances, the improvement of chemical storage conditions, and the prevention of inappropriate disposal of chemicals through proper handling and disposal of hazardous wastes greatly improves overall safety, reduces potential liability expenses, and protects the environment.

A comprehensive and effective hazardous substances management program, including hazardous waste reduction (toxics use reduction), can only be achieved through control of hazardous substances from the time of purchase through waste generation and final disposal (cradle-to-grave). Proper and complete documentation must be practiced at every stage, to promote safety, to meet legal requirements, to reduce liability, and to provide for the effective management of hazardous wastes. It is essential for all who use hazardous substances and generate hazardous wastes to cooperate fully with the Lesley University Hazardous Substances Management Program.

GOAL

This policy is to provide for a comprehensive hazardous substances and hazardous waste management program which most effectively protects human wealth, safety, and welfare, protects the environment, and incorporates hazardous waste reduction techniques. Objectives:

- To maintain control chemicals and hazardous substances to reduce excessive and wasteful ordering, to meet legal requirements for the storage and use of all substances including hazardous and toxic substances, to aid in monitoring hazardous waste generation, and to eliminate excessive amounts of outdated chemicals.
- To monitor all processes and activities that produce chemical or biological wastes to determine whether or not the wastes are hazardous wastes.
- To identify, collect, label, properly handle and store, and properly transport and dispose of through licensed transporters all hazardous wastes, universal wastes, and hazardous biological and bio-medical (biohazard) wastes.
- To maintain, complete documentation of the generation, accumulation, transportation, and disposal of all hazardous wastes, universal wastes, and hazardous biological and bio-medical (biohazard) wastes.
- To incorporate hazardous waste reduction techniques whenever possible.
- To provide an annual review process for the Guidelines for Emergency Procedures with the specific purpose of incorporating changes designed to make the plan more effective and efficient.

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SCOPE

The Lesley University Public Safety Office was created in part to address the many legal requirements for the proper handling and disposal of hazardous wastes generated on campus and in part to address campus wide safety issues. The first and most immediate tasks were to refine the existing comprehensive chemical inventory system and to develop a comprehensive hazardous waste management program for the entire campus. The program effectively manages the generation, identification, collection, labeling, handling, accumulation, transportation, and disposal of all hazardous wastes including universal wastes and biological and bio-medical wastes (biohazard wastes) as required by law and includes a system of documentation and record keeping that exceeds legal requirements thus effectively reducing the liability that Lesley University may have in this area.

Hazardous waste reduction has been achieved through an ongoing effort in toxic use reduction through the substitution of less toxic or non-toxic substances and through the reduction in the amounts of toxic substances used. Reducing the amounts of toxic chemicals used in chemistry laboratory experiments, substituting non-toxic chemicals, having students work in pairs, and using micro scale chemistry has significantly reduced the amount of hazardous wastes generated and thus the associated costs of hazardous waste removal along with reduced costs for chemical purchases. Less toxic and thus safer cleaning products and other substances used by the Physical Plant and Facilities are substituted when practical.

The Public Safety Office has developed and conducts a comprehensive program of hazardous substances management. There are three main elements of the program:

- Hazardous Substances Inventory: procurement, inventory, and storage of all chemicals and hazardous substances.
- Hazardous Waste Reduction through Toxic Use Reduction: elimination of duplication in chemical purchasing, reduction in the amounts of toxic and hazardous substances used, substitution of non-toxic or less-toxic substances, and micro-scale and small-scale chemistry initiatives.
- Hazardous Waste Management: Identification, collection, labeling, handling, accumulating, and transporting for disposal all hazardous and universal wastes and all biological and bio-medical (biohazard) wastes.

1. Hazardous Substances Inventory

The hazardous substances inventory is maintained by the Public Safety Office. The inventory currently consists of all chemicals stored and used by the Natural Sciences department. All chemical purchase orders should be routed through the Public Safety Office and that they be included in the inventory system. This would ensure that all chemicals and toxic and hazardous substances would be properly stored, their amounts and locations would be verifiable, unnecessary, and duplicative purchasing would be avoided, increased opportunities for toxic use reduction would be available, and tracking of material safety data sheets (MSDS's) is assured.

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All material safety data sheets (MSDS's) for chemicals and hazardous and toxic substances are reviewed and filed in a master file maintained by the Public Safety Office. Satellite MSDS files are maintained for substances used in a particular department or workplace.

2. Hazardous Waste Reduction (Toxics Use Reduction)

Hazardous waste reduction (toxics use reduction) has considerable benefits including less risk to faculty, staff, and students and cost savings for not having to purchase expensive chemicals, for not having to have control measures and protective equipment needed to handle the toxic or hazardous substance, and for not having the cost for disposal of the hazardous waste. It can be achieved through the elimination of duplication in chemical purchasing either through a more complete chemical inventory and purchasing system managed by the Public Safety Offices or through a review process where all chemical purchases are reviewed by the Lesley Department of Public Safety. Also, reduction in the amounts of toxic and hazardous substances used can be achieved through a determination of the least amounts necessary to meet the particular needs or through having students work in pairs for chemistry and biology laboratory experiments thus cutting the amounts of toxic and hazardous substances in half. The use of micro-scale and small-scale chemistry for laboratory experiments dramatically reduces the use of toxic and hazardous substances. Direct substitution of a non-toxic or non-hazardous substance for a toxic substance can eliminate a whole hazardous waste stream. Substitution can be used effectively in certain chemistry laboratory experiments. Also, laboratory experiments using less toxic and non-toxic chemicals can be selected over others using more toxic or hazardous chemicals. Toxics use reduction, in addition to providing a safer workplace and cost savings in the purchase and disposal of hazardous chemicals, is an integral part of the Department of Safety's University Emergency Plan and shall be reviewed annually for opportunities for improvement.

3. Hazardous Waste Management

Hazardous wastes are identified, collected, labeled, properly handled and placed in the hazardous waste accumulation area. Massachusetts Hazardous Waste Regulations, 310 CMR 30.111 (1) state: "A hazardous waste is a waste, or combination of wastes, which because of its quantity, concentration, or physical, chemical or infectious characteristics may cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness, or pose a substantial present or potential hazard to human health, safety, or welfare, or to the environment, when improperly stored, treated, transported, or disposed of, or otherwise managed." Wastes are identified and labeled as hazardous wastes based on whether they exhibit one or more of the following characteristics: ignitability, corrosiveness, reactivity, and toxicity. They are also identified as hazardous wastes based on listings on specific types or sources of hazardous wastes, or of acutely hazardous wastes. Hazardous wastes are grouped according to the Department of Transportation (DOT) hazard classes and packing groups in preparation for transporting.

There is an ongoing effort to identify all processes and activities which produce chemical, biological, and bio-medical wastes. Information contained in MSDS's pertaining to waste disposal is often misleading or inadequate or a simple statement that the substance must be disposed of in accordance with all applicable federal, state, and local environmental

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regulations. Thus, MSDS's should never be used as a guide for proper waste disposal. The Environmental Health and Safety Office determines whether or not wastes are hazardous wastes based on federal and state regulations and, for wastes not regulated by law, on hazardous properties which could present a potential human or environmental danger or create legal liability issues for Lesley University should they be disposed of improperly. A crucial element in the identification of hazardous wastes is a complete knowledge of the chemicals used and the processes or activities involved in generating the hazardous wastes. It is imperative for those who generate hazardous wastes to provide all information regarding the chemicals used and the processes or activities involved in producing the hazardous wastes. Many wastes require basic testing to determine their properties including the presence of specific chemicals or groups of chemicals which would identify them as hazardous wastes. Treatment, including neutralization, of wastes *identified as hazardous wastes under 310 CMR 30.000* is prohibited. Neutralization of non-hazardous waste between pH 2.0 and pH 12.5 is allowed. Labeling of hazardous wastes exceeds federal and state requirements and is designed to provide maximum information for safety, all information necessary for lab-packing, and maximum protection against any potential liability. Thus, Lesley University complies with the Massachusetts Hazardous Waste Regulations (310 CMR 30.000) which exceeds federal regulations, the federal Clean Water Act, Massachusetts Department of Public Health regulations, and other applicable federal and state regulations.

Hazardous wastes which qualify as universal waste are managed according to the Massachusetts Standards for Universal Waste Management 310 CMR 30.1000. Universal wastes include certain batteries such as NiCd and silver batteries (button batteries); pesticides including mercury based pesticides, arsenic based pesticides, chlorinated pesticides, and banned or suspended pesticides; thermostats containing mercury; mercury containing devices such as manometers, switches, water meters, thermometers, and gauges; and mercury containing lamps. If you are not sure whether an item is a universal waste, you should consult the Lesley University Department of Public Safety.

Biological waste and bio-medical waste which as biohazard wastes are managed under the Massachusetts Department of Public Health regulations "Storage and Disposal of Infectious or Physically Dangerous Medical or Biological Waste State Sanitary Code Chapter VIII" 105 CMR 480.000. The Environmental Health and Safety Officer is responsible for making sure that the responsible owner of the satellite accumulation area takes the waste from the satellite accumulation area and places the waste in the central storage area. The waste must then be properly handled, packaged, labeled, and placed in the appropriate accumulation area, and arrangements made for their transportation to a licensed disposal facility.

The Public Safety Office is responsible for making arrangements for the lab-packing and transportation of all hazardous wastes. Transportation and disposal of hazardous wastes is performed by licensed transporters. All state and federal regulations must be complied with. Some hazardous wastes are transported in bulk drums, while most hazardous wastes are lab-packed into open head drums for transportation and eventual disposal. Documentation is a key element of hazardous waste management. Label information is of primary importance for safety, lab-packing information, and inventory purposes. A hazardous waste inventory list is prepared prior to transportation and disposal. Hazardous waste manifests are prepared at the

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time the hazardous wastes are lab packed and transported from Lesley University to the hazardous waste facility. The waste profiles, manifests, and other records as required by law become the final element of documentation and must be kept in a central location which is the Environmental Health and Safety Office.

All documentation including that which is legally required is maintained for each shipment. The Lesley University Department of Public Safety is responsible for making arrangements for the transportation of all universal wastes to recycling facilities.

Arrangements With Local Boards, Departments, Hospitals, and Emergency Response

Teams:

Massachusetts hazardous waste regulations, 310 CMR 30.351 (9) (j) (1-4) require generators of hazardous waste to make "arrangements to familiarize police departments, fire departments, local boards of health, and emergency response teams with the layout of the site, properties of hazardous waste handled at the site, hazards associated with such wastes, places where personnel at the site would normally be working, entrances to and roads inside the site, and possible evacuation routes." Also, "arrangements with state emergency response teams, emergency response contractors, local boards of health, and equipment suppliers" must be made as well as "arrangements to familiarize local hospitals with the properties of hazardous waste handled at the site and the types of injuries and illnesses which could result from fires, explosions, or other releases at the site."

Satellite Accumulation Areas

There are a number of satellite accumulation areas (satellite points) for hazardous wastes generated at specific locations in Lesley University. One container is used per waste stream at each satellite point. Although the maximum capacity of the container allowed in the regulations is fifty-five (55) gallons, the actual container size per waste stream ranges from one hundred (100) milliliters to fifty-five gallons. All satellite points have spill control material available. The person responsible for the generation of hazardous waste at each satellite point is responsible for ensuring that the container for each waste stream is properly labeled, that the accumulation start date is entered on the label when the container is full, and that the waste be taken to the hazardous waste accumulation area within three days.

Satellite points for hazardous waste are located as follows:

Department	Location
Art	AIB, Printmaking Lab
Art	AIB, Photography Lab
Art	AIB
Biology	UHall
Biology	UHall
Facilities	Garage

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Facilities

Power Plant

Most buildings have satellite points for universal waste (primarily spent fluorescent lamps for recycling).

Hazardous wastes in satellite accumulation areas are also monitored by the Lesley University Public Safety Office to prevent the mixing of incompatible wastes, different waste streams, and types of wastes and the accumulation of incompatible wastes in the same location. All labels on hazardous waste containers must be properly completed.

Hazardous Waste Accumulation Area

The hazardous waste accumulation area is located in [?]. The room also serves as the chemical storage area and has a sealed floor to provide containment, fire suppression system, sufficient heating and cooling to provide a temperature of approximately 65 to 70 degrees Fahrenheit. Spill control material is available for all chemical spills. The room is properly posted with hazard placards and signs for chemical storage, hazardous waste, and exists. Emergency telephone numbers are posted near the telephone. Inspections of the hazardous waste accumulation area are conducted weekly and an inspection log is kept for each inspection.

Contingency Plan, Emergency Procedures, Preparedness, and Prevention

Lesley University has the capacity for over 42,000 gallons of fuel oil in underground storage tanks and has a Spill Prevention, Control, and Countermeasures (SPCC) Plan as required by 40 CFR 112, Oil Pollution Prevention. In addition, specific spill control materials for the substances used and the hazardous wastes generated are made available at hazardous waste generation sites, satellite points, and the hazardous waste accumulation area. Workers at these locations are made familiar with the spill control materials and emergency systems.

[The Office of Public Safety is currently reviewing the above policies and procedures. Please contact the Office of Public Safety with any further questions:
http://www.lesley.edu/security/security_home.htm]

TRAINING

The Massachusetts Hazardous Waste Regulations, 310 CMR 30.000, requires training for personnel assigned to hazardous waste management for small quantity generators (SQG's). Section 30.516 of the regulations states that personnel assigned to hazardous waste management "shall successfully complete a program of instruction or on-the-job training that teaches them to perform their duties in a way that ensures that facility's compliance with 310 CMR 30.000 and the condition of the facility's license". The instruction shall include hazardous waste management procedures including contingency plan implementation. New personnel cannot work unsupervised until they have received the proper training which must be completed

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within six months of their employment of assignment to hazardous waste management. Personnel shall also have an annual training review. All training records of current personnel shall be kept until closure of the facility and those of former personnel shall be kept for at least three years from the time they last worked at the facility. A written personnel training plan is required to ensure compliance with 310 CMR 30.516 (1). To ensure that personnel are able to respond effectively to emergencies, the training plan, at a minimum, shall specify how personnel will be familiarized with the properties and hazardous nature of the hazardous wastes at the facility and with emergency procedures, emergency equipment, emergency systems, and personal safety equipment. Procedures for using, inspecting, repairing, and replacing the facility's emergency and monitoring equipment; use of automatic waste feed cutoff systems; communications or alarm systems; response to fire or explosions; response to potential ground water or surface water contamination incidents; and shutdown of operations shall be included where applicable.

Generator status determines training needs. For small quantity generators (SQG's) a written training plan is not required for personnel assigned to hazardous waste management. Also, a written contingency plan is not required. Lesley University is currently a small quantity generator; however, generator status can change. Should the college become a large quantity generator, it shall be university policy that personnel assigned to hazardous waste management receive formal training within six months of the generator status change and annual training review thereafter as required by 310 CMR 30.000. Personnel in SQG facilities responsible for hazardous waste management can always benefit from training; more training is better than less.

PROCEDURES FOR HANDLING CHEMICAL WASTE*

[The Office of Public Safety is currently reviewing these policies and procedures. Please contact the Office of Public Safety with any further questions:

http://www.lesley.edu/security/security_home.htm]

HAZARDOUS WASTE AND UNIVERSAL WASTE

- Label waste containers clearly and completely with "CHEMICAL WASTE", "HAZARDOUS WASTE", or "UNIVERSAL WASTE"; the contents; the date (accumulation start date**); "HANDLE WITH CARE"; all specific hazards (flammable, oxidizer, corrosive, toxic, etc.); and all of the following which may apply: course, experiment, professor, and room number. Printed labels are available from the Environmental Health and Safety Office.
- Do not fill waste containers to the top.
- Cap waste containers tightly, especially if any volatile organic chemicals are present.
- Provide a copy of the laboratory experiment or the chemicals that went into the waste for each laboratory experiment. The Environmental Health and Safety Officer will

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determine whether or not the chemical waste is hazardous waste and provide the proper packaging and hazardous waste handling.

- The accumulation start date must be entered on the label of the container at the satellite point (satellite accumulation area) when the container becomes full.

Procedures for Handling Biological and Bio-Medical Waste

- All biological and bio-medical waste, including all treated biological and bio-medical waste, must be placed in an approved red bag with an approved biohazard label.
- All sharp objects must be placed in approved sharps containers with an approved biohazard label.

Labeling

The Massachusetts Right-to-Know Law requires that all containers of more than five pounds or more than one gallon containing toxic or hazardous substances in the workplace must be labeled with the chemical name of the substance. For mixtures, the label must include the chemical name of each toxic or hazardous constituent if that constituent comprises one percent or more (two percent or more if an impurity) of the mixture. Also, labels must be clear, prominent, in English, and weather resistant. Containers must include the NFPA symbol with appropriate hazard rating if available.

The Occupational Safety and Health Administration (OSHA) regulations, 29 CFR 1910, require that labels include the identity of the substance (the name of the product as it appears in the MSDS), health hazard warnings for all hazards (including target organ health effects), physical hazard warnings (i.e. flammable, corrosive, oxidizer, and reactive), and for manufacturers and distributors, the name and address of the responsible party, should additional information be needed. The policy of the Massachusetts Department of Labor and Workforce Development, Division of Occupational Safety is that containers labeled in accordance with the OSHA Hazard Communication Standard will also be considered to satisfy the labeling requirements of the Massachusetts Right-to-Know Law.

The National Research Council recommends labels showing the contents of the container and associated hazards. There are many specific labeling requirements both for groups of substances with specific hazards and for specific individual substances. The many labeling requirements can occasionally cause confusion and inadvertent mislabeling. Labeling of toxic or hazardous substances is a very important function and is essential for your protection and the protection of your fellow workers and others who might come in contact with the substance. Even very small quantities of many substances can be harmful or even cause severe injury or health risk. Substances placed in temporary unlabeled containers for immediate use are an accident waiting to happen, should the container be set down for even a minute and someone not knowing the contents picking up the container. To avoid confusion and to reduce risk to yourself and the others in your workplace, the following is essential:

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- All containers, regardless of size, must be labeled with the name of the substance (chemical formulas and structural diagrams are not legally acceptable).
- To the extent possible, all labels must show the health hazards and the physical hazards associated with the substance.
- If you find an unlabeled container and are unsure of its contents, notify the Department of Public Safety at ext. 8888.

ANNUAL REVIEW

The three substances of the Hazardous Substances Management Plan (Hazardous Substances Inventory, Hazardous Waste Reduction through Toxics Use Reduction, and the Hazardous Waste Management) shall be reviewed annually for the purpose of improving this plan and for making hazardous substances management more effective and efficient. Annual review checklists shall be developed to aid in the process. In addition, periodic comprehensive independent environmental audits shall also review the plan. Changes in the plan shall be documented as to the reason for the change as well as the reason for the original language. Thus, a history of the Hazardous Substances Management Plan can be established with earlier and subsequently replaced language being documented for future inclusion in the plan should it be found that it was more suitable.

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IX. TIME AND EFFORT REPORTING

Lesley's policy is to comply with all applicable federal regulations and guidance regarding time and effort reporting to ensure good stewardship of the funds provided to the University for grants and sponsored projects. The University's effort distribution system and certification reporting system requires that all effort directly associated with a sponsored program be classified consistently, regardless of whether the salary is charged to the sponsor or to the cost shared by the University.

As a condition of receiving funding from the federal government, the University is required to maintain and certify the percentage of effort employees devote to externally-sponsored projects. The University's effort reporting system is an after-the-fact system requiring the completion of an Effort Reporting form (see below).

Faculty and staff are expected to commit some level of effort (i.e., greater than 0%) on proposals in which they are listed as Principal Investigator, or key personnel. Since these roles assume responsibility for the scientific, administrative, and financial management of an award, it is assumed that fulfilling these responsibilities requires time and effort. However, there are instances in which certain types of proposals do not require individuals to commit any level of effort. These exceptions include equipment and instrumentation grants, student augmentation grants, and faculty training grants.

Faculty and professional staff shall complete an Effort Reporting Form near the end of each academic term. Hourly staff shall complete bi-weekly time sheets to certify their effort.

WHAT IS EFFORT?

An individual's effort is defined as the percentage of time spent on a particular work-related activity, such as instruction, research, advising, administration, etc., for which the individual is compensated by the University.

WHAT IS EFFORT REPORTING?

White House Office of Management and Budget (OMB) federal regulation *OMB Circular A21* requires that Lesley University certify the effort for each employee who expended effort on a federally-sponsored project. Incomplete or improper reporting of effort is a compliance violation that could result in audit disallowances and/or withholding of federal research funding.

The *percentage of effort* on an Effort Report should be consistent with commitments made by the individual to the sponsor. The Effort Report also compares the *percent of effort* spent on a project and the *percent of salary* charged to that project. The *percent of effort* spent on a federally-sponsored project should not be less than the *percent of salary* charged to the project.

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Example of Effort Reporting Form

Quarterly Accounting of Effort Reporting on Grants

Period	Quarter 2, FY2011		
Employee Name:	Jane Doe		
Quarterly Earnings	\$	25,595.00	
Project	<u>3-1893 - The Inquiry Project</u>	\$10,174.23	40%
Project	<u>3-1971- The Answer Project</u>	\$ 0	0%
	Department Code: 1-1850	\$15,420.77	60%

This accounts for effort in accordance with standard employment contracts or agreements and does not include honorarium or consultant related payments (expense vouchers). The employee listed is spending time on the projects (grants and instruction) identified above. The following undersigned certifies to the best of their knowledge and belief that the employee named above expended effort in the amounts and percentages listed. Further, the employee & supervisor certifies that the time worked on grants can be adequately documented by personal time logs or an analysis of products or output prepared.

Employee Signature

Date:

P.I., Project Manager, or Supervisor Signature

Date:

- The report shall reasonably reflect the percentage distribution of time and effort expended by faculty and professional staff involved in externally-sponsored projects.
- The report shall be completed and signed by each faculty and professional staff working on an externally-sponsored project. Faculty and staff must document the time and effort spent on the project regardless of whether the sponsor pays for the time or the time is cost-shared by LU.
- The report shall be confirmed by a person having firsthand knowledge of the employee's activities. Confirmation is indicated by a countersignature on the form.
- The report shall not be completed for employees who submit time sheets.

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Failure to submit the Time and Effort Certification Form may result in the suspension of grant activity.

Effort Reporting Schedule

Effort Reports are generated on a semi-annual and quarterly schedule, depending on an individual's classification. The below graphic shows the six (6) Reporting Periods for the year (2) for Academics and (4) for non-Academics.

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Academics	Academic Spring						Academic Fall					
Non-Academics	Non-Academic Winter			Non-Academic Spring			Non-Academic Summer			Non-Academic Fall		

All faculty receive Effort Reports on a semi-annual **Academic schedule** for the following periods:

- Academic Spring: January – June
- Academic Fall: July – December

All other staff receive Effort Reports on a quarterly **Non-Academic schedule** for the following periods:

- Non-Academic Winter: January – March
- Non-Academic Spring: April – June
- Non-Academic Summer: July – September
- Non-Academic Fall: October – December

Effort Reporting Cycles and Dates

There are four effort reporting cycles a year. The below chart details which Effort Reports are included in each cycle, the deadline for reports to be issued, and certification deadlines.

Reporting Cycle End Date	Effort Reports included in cycle	Issuance Deadline (45 days)	Certification Deadline (30 days)
March 31	Non-Academics	May 15	June 14
June 30	Academics + Non-Academics	August 14	September 13
September 30	Non-Academics	November 14	December 14
December 31	Academics + Non-Academics	February 14	*March 16/17

*depending on Leap Year

EFFORT REPORTING POLICY

Each school's budget officer shall maintain the University-approved system of after-the-fact confirmation to substantiate salary costs that are directly charged to federally funded projects consistent with the following standards:

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Certification of Effort by Principal Investigators and Other Faculty in Professorial, Professional Research, and Management Titles

Principal Investigators and other faculty in Professorial, Professional Research, and Management titles who are paid on federal or federal flow-through funds are required to certify their own effort since they are in the best position to understand how they are spending their time in support of the various activities in which they are engaged. This is consistent with the OMB Circular A-21 requirement that the distribution of salaries and wages be supported by activity reports that are confirmed by "a responsible person with suitable means of verification that the work was performed."

Note: PIs and other professionals must certify their own reports. Academics such as post-docs and students were not intended to be included in this group- their effort can be certified by someone with first-hand knowledge of the work performed. Staff are not asked to certify their own effort.

Treatment of Effort Reporting Revisions

Changes to previously certified Effort Reports should be extremely rare. However, if an effort report is determined to be in error, a new one can be prepared coincident with payroll cost transfers and other extenuating circumstances. Such revisions are subject to a "facts and circumstances" review and must be processed on a timely basis consistent with federal regulations and University policy (within 120 days of incurring the costs) to ensure their allowability under audit. If revisions are required after 120 days, the extremely unusual extenuating circumstances surrounding the need for a corrected effort report must be fully explained and documented.

Timeliness of Certifications

Effort Reports should be issued for certification by a center, department, or OGSP no more than 45 days after the close of the reporting period and certified within 30 days of their issuance to ensure that federal compliance expectations are met.

Preciseness of Certifications

OMB Circular A-21 provides for "a degree of tolerance" in the preciseness of effort reporting. A precise assessment of factors that contribute to costs is not always feasible, nor is it expected. An individual at Lesley may thus certify a level of effort for an award or activity that is within +/- 5% of their best estimate of the actual effort expended during the reporting period.

Allowability of Supplemental Compensation

Federal rules and regulations, including OMB Circular A-21, do not allow for an individual's institutional base salary to be increased as a result of obtaining grant funding. These federal rules and regulations also restrict the payment of overload, bonus or other payments outside the individual's institutional base salary. In addition to the University's general policy regarding the allowability of supplemental compensation, the following principles must be applied when salary is to be paid from a sponsored project.

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Charges for work performed on sponsored agreements by faculty members must be based on the individual faculty member's regular compensation during the period of performance. The only exception to allow for compensation above the base salary during the academic year is a very specific exception for consultation across departmental lines.

The general rules for faculty compensation during the academic year and the specific requirement for the exception to those rules are found in OMB Circular Act 21, section J.10.d and are as follows:

Salary rates for academic year. Charges for work performed on sponsored agreements by faculty members during the academic year will be based on the individual faculty member's regular compensation for the continuous period which, under the policy of the institution concerned, constitutes the basis of his salary. Charges for work performed on sponsored agreements during all or any portion of such period are allowable at the base salary rate. In no event will charges to sponsored agreements, irrespective of the basis of computation, exceed the proportionate share of the base salary for that period. This principle applies to all members of the faculty at an institution.

Since intra university consulting is assumed to be undertaken as a university obligation requiring no compensation in addition to full time base salary, the principle also applies to faculty members who function as consultants or otherwise contribute to a sponsored agreement 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 regular departmental load, any charges for such work representing extra compensation above the base salary are allowable provided that such consulting arrangements are specifically provided for in the agreement or approved in writing by the sponsoring agency.

These rules are no applicable to summer salary for nine (9) month faculty. See OMB circular A-21 J.10.d (2)(a). Research compensation during the summer months or other periods not included in the base salary period is to be calculated for each faculty member at a rate not in excess of the base salary divided by the period to which the base salary relates.

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X. SUBRECIPIENT MONITORING

The policy also outlines the responsibilities of the Principal Investigator in assuring both programmatic and fiscal compliance of subrecipients to the terms and conditions established by the sponsoring agency.

PURPOSE

This policy seeks to:

- promote stewardship of funds used to pay subrecipient organizations;
- promote appropriate responsibility and accountability for contractual subrecipient relationships;
- promote compliance with federal, state, University, and other legal requirements related to subrecipient monitoring; and
- ensure that the University and its sponsors receive value for funds expended.

As required by OMB Circular A-133, all subawards issued by the University shall provide the best information available to describe the award, including:

- Catalog of Federal Domestic Assistance (CFDA) title and number
- Award name and number
- Name of federal agency

The University is obligated to advise subrecipients of requirements that are imposed on them by federal laws, regulations, and the provisions of the sponsored project award document. Subrecipients are required to permit the University and its auditors to have access to records and financial statements pertaining to the subaward.

Except in unusual cases, subrecipients must be identified in the proposal submitted to the sponsoring agency. Following the execution of subawards, the University is required to monitor the subrecipient's activities to ensure that activities are conducted in compliance with regulations and that performance goals are achieved. In general, when a significant percentage of an award is passed through the University to a subrecipient, more intense monitoring is necessary. Regular communication with the subrecipient is required.

The University shall monitor subrecipients to ensure compliance with audit requirements. If audit findings are revealed, the University shall issue a management decision within sixty days following the receipt of the subrecipient's audit report and confirm that the subrecipient has taken appropriate corrective actions in a timely manner. If the subrecipient's corrective action plan is not submitted to the University within thirty days, the subrecipient will receive a follow-up phone call or email from the school's budget officer, or the OGSP grants officer. If the corrective action plan is not received by the end of sixty days, a letter will be sent from the Associate Provost. After ninety days, a letter will be sent from University Counsel to inform the subrecipient that failure to respond may result in the termination of the subaward.

If the subrecipient's audit findings necessitate adjustments in the University's financial records, such adjustments shall be made in a timely manner.

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A-133 CERTIFICATIONS

1. Non-profit subrecipients who expended \$500,000 or more in federal funds during the previous fiscal year are required to have an A-133 audit on an annual basis or may elect to have a program-specific audit. OGSP shall request annual A-133 certifications from all subrecipients. This certification requires that subrecipients certify that their A-133 audits revealed no questionable findings or provide a detailed disclosure of findings.
2. Subrecipients who are not subject to A-133 audit requirements shall complete a financial disclosure and shall be required to submit in a program specific audit, performed by an independent external entity, upon request by the University.
3. If audit findings are revealed, OGSP shall issue a management decision within sixty days of notification and shall provide additional monitoring to ensure that timely and appropriate corrective actions are taken in response to audit findings.
4. Internal Audit shall provide assistance with issuing management decisions and ensuring that appropriate corrective actions are taken.

SUBAWARD CHANGES

1. Subrecipients are required to notify the University and obtain prior written approval from their school's budget officer or the OGSP grants officer for any changes that may materially alter the terms of the subaward. Examples include, but are not limited to, changes in the period of performance, scope of work, or budget.
2. The Principal Investigator shall work with the subrecipient to ensure that any changes that may materially alter the terms of the subaward are immediately reported to OGSP for approval or the school's budget officer.
3. OGSP and/or the school's budget officer shall provide approval in a timely manner; in most cases, a formal subaward amendment will be required.

THIRD-TIER SUBCONTRACTERS

1. When subrecipient budgets include funds for contractual purposes, the Principal Investigator shall work with the subrecipient to facilitate the timely provision of required documentation to OGSP and/or the budget officer.
2. OGSP and/or the school's budget officer shall review third-tier subcontractors included in subaward budgets, request identification of the entity by name, request justification for how the entity was selected (i.e., evidence of competitive bid process or sole source justification), and provide the subrecipient with written approval prior to the subrecipient entering into a contractual relationship with a third-tier subcontractor.
3. OGSP and/or the school's budget officer shall request any additional documentation from the subrecipient needed to make an informed decision about the approval of third-tier subcontractors.

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CONTRACT REVIEW

The Office of University Counsel shall review all subawards with variations from the approved subaward template. University Counsel shall work with the Principal Investigator and OGSP and/or the school's budget officer to negotiate changes to proposed subawards prior to their execution.

COMMUNICATION WITH SUBRECIPIENT

The Principal Investigator shall maintain sufficient contact with the subrecipient to assess accurately whether the subrecipient is adequately performing the statement of work and reasonably progressing towards the achievement of the performing goals.

REVIEW OF TECHNICAL PERFORMANCE REPORTS

The Principal Investigator shall obtain periodic written performance reports from the subrecipient. Such reports should generally contain a comparison of actual accomplishments with the goals and objectives established for the period.

REVIEW OF FINANCIAL INVOICES

1. Upon receipt of financial invoices, the Principal Investigator shall review and assess whether the charges on the invoice reasonably match progress made on the project. If an invoice is believed to be inaccurate, Principal Investigators shall contact the subrecipient for clarification and request additional documentation before forwarding the invoice to Grant Accounting for payment.
2. Prior to approving and issuing payments on subawards, a financial officer shall review financial invoices for compliance with sponsor guidelines and the terms of the subaward.
3. A financial officer shall work with the Principal Investigator and subrecipient to secure any additional documentation needed to process invoice payments and shall withhold payment on invoices until such documentation is received.

SITE VISITS

Depending on the scope of the work and level of involvement from the subrecipient, site visits are often necessary to ensure an effective collaboration. The Principal Investigator shall arrange and maintain documentation for such visits.

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FINANCIAL DISCLOSURE STATEMENTS

Lesley University

Disclosure of Significant Financial Interest

A separate form is required for each entity which represents a significant financial interest. This information must be updated annually or when reportable significant financial interest occurs.

Investigator Name: _____ Dept.: _____

EITHER: I have no significant financial interest

OR: I am reporting significant financial interest below

Remuneration amount: _____ Source: _____

Type of Organization (e.g., pharmaceutical firm; biotech firm; engineering company; software company, etc.) _____

Nature and amount of Remuneration that is greater than

\$5,000: _____

Salary: _____ Royalties: _____

Licensing: _____ Consulting: _____

Honoraria: _____ Other: _____

Types of holdings whose fair market value is greater than \$5,000 or more than 5% of ownership interest:

Stocks/Stock Options: _____

Patents/Copyrights: _____

Other: _____

Investigator's Signature:..... Date:

Policies and Procedures for Grants and Sponsored Projects

XI. RESPONSIBLE CONDUCT IN RESEARCH

Responsible conduct in research is an imperative for Lesley University's faculty and students. With or without federal mandate the institution would embrace the opportunity to augment educational programming with this very important aspect of research.

THE NIH: According to the NIH's notice "Update on the Requirement for Instruction in the Responsible Conduct in Research" Notice Number: NOT-OD-10-019, dated 11/24/09, upon award of any NIH Institutional Research Training Grants, Individual Fellowship Awards, Career Development Awards, Research Education Grants, Dissertation Research Grants or other grant programs with a training component that requires instruction in responsible conduct in research as noted in the Funding Opportunity Announcement, a formal training program which includes at least 8 hours of contact hours (face to face engagement) between faculty and trainees is required. This training program should be provided throughout the trainees' scientific career and should occur as an undergraduate, graduate, and post-doc student, as well as during Career Awards and other milestones in a scientist's career.

THE NSF: Pursuant to the 2007 America COMPETES Act, the National Science Foundation (NSF) has adopted a new certification requirement that becomes effective January 4, 2010. The new NSF Grant Proposal Guide states: "When submitting a proposal to NSF, the Authorized Organizational Representative is required to complete a certification that the institution has a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research." The plan must also include a system to verify that the training has occurred. The plan does not have to be submitted with proposals, but NSF could request it at any time- and NSF could audit compliance. Currently, institutions are free to develop their own plans. For more information, go to www.lesley.edu/provost/provost.html.

To assist faculty in the development of a training program, Lesley University uses the NIH online training certificate program. The modules included in the NIH online training can be used to guide and augment responsible conduct in research training in addition to face-to-face didactic interactions with students. Adequate training includes the following components:

- a. Conflict of interest: personal, professional, and financial
- b. Policies regarding human subjects, live vertebrate animals in research and safe laboratory practices
- c. Mentor/mentee responsibilities and relationships
- d. Collaborative research including collaborations with industry
- e. Peer review
- f. Data acquisition and laboratory tools; management, sharing and ownership

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- g. Research misconduct and policies for handling misconduct (please see LU's policy)
- h. Responsible authorship and publication
- i. The scientist as a responsible member of society, contemporary ethical issues, in biomedical research, and the environmental and societal impacts of scientific research

It is incumbent upon the Principal Investigator of an NIH and/or NSF award requiring responsible conduct in research training to prepare, administer and document the training provided to students involved in research.

1. Faculty Principal Investigators (PIs) have the primary responsibility for training the students involved in their NSF-funded research. The Preliminary Grant Approval Form requires a signature from any PI who submits an NSF proposal that requests funding for undergraduate students. This signature indicates that the PI agrees to participate in appropriate RCR training.

2. Responsible Conduct of Research (RCR) training will be required for all undergraduate receiving wages (or working as volunteers) or receiving academic credit for participating in NSF-funded research. Training must be completed within the semester or summer that the undergraduate begins work on the NSF-funded research. RCR training will be documented on a form developed for that purpose, signed by both the PI and the undergraduate. This RCR form will be maintained by the Institutional Review Board (IRB) until the IRB learns that documentation is no longer needed. RCR training will include the following components:

- a) Each student must successfully complete the appropriate National Institute of Health module of RCR training. The National Institute of Health computer based training option is available 24 hours a day at no cost. Upon completion of the self-guided study and test a certificate can be printed. Students may access this Website at:

<http://grants.nih.gov/training/responsibleconduct.htm>

This requirement can be waived by the Associate Dean for students who have successfully completed an RCR workshop at Lesley or another institution designed to satisfy NSF's training requirement or other comparable training; the Associate Dean will specify what constitutes appropriate documentation in these cases. Successful completion should be documented by completing the RCRT Form and attaching a certificate generated by the online training program or by other documentation acceptable to the Associate Dean.

- b) PIs will certify on the RCRT form that the student has received RCR training appropriate to the search and discipline.

3. The Finance or Grants Officer will notify the IRB when the University receives a grant from the National Science Foundation, providing the name of the PI and the NSF grant number. PIs give the Associate Dean periodic updates listing the students participating in the research. The

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Dean of Faculty will facilitate this process by sending reminder emails to all faculty who are PIs on NSF grants at the beginning of each semester and before summer research begins.

4. The Lesley University academic deans may amend this plan at any time after consultation with the Associate Provost and/or Dean of Faculty. Details of any amended plan will be sent to all faculty with NSF grants, the Grants Officer, the Associate Dean, and the Finance Office and will be posted on the Provost's website. At a minimum, the plan will be reviewed and updated annually, no later than July 1 of each year (beginning July 1, 2010).

5. The Associate Dean in consultation with the Dean of Faculty and the Associate Provost will make decisions on a case-by-case basis about students whose only participation in NSF funded research falls into one of the following situations:

- the active NSF grant funds equipment used in courses to provide research training
- the active NSF grant funds research that is incorporated into the research training provided to students in a course

To access the training module, please complete the RCR training form and follow the RCR training form and follow the instructions for your RCR training.

RESPONSIBLE CONDUCT OF RESEARCH TRAINING POLICY

BASIC PRINCIPLES:

Lesley University is committed to the ethical conduct of research and is in compliance with Section 7009 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education and Science (America COMPETES) Act which requires that an institutional plan be in place to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers participating in National Science Foundation (NSF) funded research projects.

APPLICATION:

The Principal Investigator (PI) will be responsible for providing appropriate RCR training to undergraduate and graduate students and post doctoral employees who are working on the PI's NSF-funded projects. At this point, only those students and post docs who are part of a NSF-funded project are required to undergo RCR training.

Principal Investigators will be trained on the RCR policy by the Institutional Review Board (IRB).

DEFINITIONS:

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Principal Investigator can also be known as the co-investigator (for collaborative grants) or the project director and is the faculty member or administrator responsible for directing the work of the NSF grant project at Lesley University.

Educational training can be offered as various activities such as lectures, workshops, online courses, discussion groups, or any other educational activity approved and tracked by the IRB.

The core instructional areas (modules) of the Responsible Conduct of Research as indicated by the U.S. Office of Research Integrity are:

- **Data Acquisition, Management, Sharing, and Ownership:** Accepted practices for acquiring and maintaining research data. Proper methods for record keeping and electronic data collection and storage in scientific research. Includes defining what constitutes data; keeping data notebooks or electronic files; data privacy and confidentiality; data selection, retention, sharing, ownership, and analysis; data as legal documents and intellectual property, including copyright laws*.

* See "PHS Policy on Instruction in the Responsible Conduct of Research":
http://ori.dhhs.gov/policies/RCR_Policy.shtml

- **Conflicts of Interest and Commitment:** The definition of conflicts of interest and how to handle conflicts of interest. Types of conflicts encountered by researchers and institutions. Includes topics such as conflicts associated with collaborators, publication, financial conflicts, obligations to other constituencies, and other types of conflicts.
- **Human Subjects:** Issues important in conducting research involving human subjects. Includes topics such as the definition of human subjects research, ethical principles for conducting human subjects research, informed consent, confidentiality, and privacy of data and patient records, risks and benefits, preparation of a research protocol, institutional review boards, adherence to study protocol, proper conduct of the study, and special protections for targeted populations, e.g., children, minorities, and the elderly.
- **Animal Welfare:** Issues important to conducting research involving animals. Includes topics such as definition of research involving animals, ethical principles for conducting research on animals, Federal regulations governing animal research, institutional animal care and use committees, and treatment of animals.
- **Research Misconduct:** (fabrication or falsification of data including image manipulation, plagiarism). The meaning of research misconduct and the regulations, policies, and guidelines that govern research misconduct in PHS-funded institutions. Includes topics such as fabrication, falsification, and plagiarism; error vs. intentional misconduct; institutional misconduct policies; identifying misconduct; procedures for reporting misconduct; protection of whistleblowers; and outcomes of investigations, including institutional and Federal actions.
- **Publication Practices and Responsible Authorship:** The purpose and importance of scientific publication, and the responsibilities of the authors. Includes topics such as collaborative work and assigning appropriate credit, acknowledgements, appropriate citations, repetitive publications, fragmentary publication, sufficient description of

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methods, corrections and retractions, conventions for deciding upon authors, author responsibilities, and the pressure to publish.

- **Mentor/Trainee Responsibilities:** the responsibilities of mentors and trainees in pre- and postdoctoral research programs. Includes the role of a mentor, responsibilities of a mentor, conflicts between mentor and trainee, collaboration and competition, selection of a mentor, and abusing the mentor/trainee relationship
- **Peer Review:** The purpose of peer review is to determine the merit for research funding and publications. It includes topics such as, the definition of peer review, impartiality, how peer review works, editorial boards and ad hoc reviewers, responsibilities of the reviewers, privileged information and confidentiality.
- **Collaborative Science:** A number of research issues may arise when scientists collaborate. As a result, this approach to science includes topics such as setting ground rules early in the collaboration, avoiding authorship disputes, and sharing materials and information with internal and external science partners.

Only those instructional areas applicable to the grant funded research project are required to be covered. For example, a chemistry project might not involve the use of human subjects; the human subjects module would therefore not be required as part of the training.

ADMINISTRATION:

Dissemination and administration of these regulations will be the responsibility of the Associate Provost. The IRB will provide support in developing and offering training and resources to the Principal Investigators; track who has been trained; monitor the regulations; assess the program; make recommendations; and keep current on federal regulations pertaining to this policy.

RESEARCHER MENTORING PLAN

In order to provide the fullest orientation to research grant processes and procedures, and to enhance the understanding and collaboration of all those working on sponsored research, Lesley University has implemented a Mentoring Plan. Mentoring is required in the preparation for new faculty and students, undergraduate, graduate or post-doctoral, who take part in grant-funded research projects.

The Mentoring Plan includes the following elements:

1. A senior faculty is identified by the Dean of Faculty to serve as a "Mentor Sponsor" who has responsibility for maintaining contact with the mentee, providing institutional knowledge, and acting as the primary resource for any problems or questions that arise during the research project.
2. Mentees and mentors meet before the beginning of a grant process that involves the mentee. The meeting serves to review key elements of the Mentoring Plan, to build a community of researchers, and to present a panel of experienced Lesley researchers sharing their work.

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3. Four additional meetings are scheduled within the first semester a student or post-doc is involved with the project to cover important information about sponsored research processes. These sessions are held in 2 1/2 hour blocks, throughout the semester, and are facilitated by appropriate faculty or research office personnel. Topics include:

- Preparation of grant proposals and publications. This will include the review of successful proposals and their publications, as well as guidelines for turning research questions into successful proposals.
- Collaborating with researchers from diverse backgrounds and disciplines. Conversations about intercultural communication and respect for differences will shape this topic.
- Responsible professional and ethical practices. Based in the federal guidelines for research with human subjects, this conversation will center on criteria for ethical practices in research.
- Guidelines for effective teaching skills. Theory-based practice based in empirical research relies on connections between research and practice. This meeting will include strategies for informing teaching through research.

4. Feedback Process: At the end of the semester, an evaluation is sent to each mentor sponsor and mentee, to gather feedback about their experience and learning. This evaluation is used to make any changes in the Mentoring Plan for the next semester.

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RESPONSIBLE CONDUCT OF RESEARCH TRAINING FORM FOR STUDENTS AND POST-DOCS

Name:		Lesley ID:	
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Status:

<input type="checkbox"/> Undergraduate	<input type="checkbox"/> Graduate	<input type="checkbox"/> Post Doc/Other
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This Lesley researcher has received basic research training in this discipline:

<input type="checkbox"/> Arts & Humanities	<input type="checkbox"/> Social, Behavioral, & Education
<input type="checkbox"/> Physical Sciences & Mathematics	<input type="checkbox"/>

And in the following RCR Modules:

<input type="checkbox"/>	Animal Welfare
<input type="checkbox"/>	Collaborative Science
<input type="checkbox"/>	Conflicts of Interest and Commitment
<input type="checkbox"/>	Data Acquisition, Management, Sharing, and Ownership
<input type="checkbox"/>	Human Subjects
<input type="checkbox"/>	Mentor / Trainee Responsibilities
<input type="checkbox"/>	Peer Review
<input type="checkbox"/>	Publication Practices and Responsible Authorship
<input type="checkbox"/>	Research Misconduct

Through the following methods:

<input type="checkbox"/>	NIH Online Training
<input type="checkbox"/>	Instructor Training (specify instructor):
<input type="checkbox"/>	Other (specify):

Certified by:

PI Name:	
Signature:	
Today's Date:	

This form is required for all students and post-docs working on a NSF Grant. Completed forms should be returned to the Institutional Review Board at irb@lesley.edu

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XII. COST TRANSFERS

Provision of timely, comprehensive and accurate reporting of the fiscal status of an award is key to ensuring that correct expenditures are applied to the award. These expenditures must be allowable, allocable, reasonable and within the term dates of the award. Other sponsor specific restrictions may apply.

Although it is ultimately the Principal Investigator's responsibility to ensure the fiscal and programmatic management of an award or contract, the department budget coordinators facilitate this endeavor by providing timely, comprehensive and accurate fiscal reports of all awards and contracts. Errors should be identified either by the budget coordinator or the PI within 30 days of posting, but no later than 90 days from posting for correct journal entries to be created with a justification as to how the error transpired. Should the identification of an error exceed 90 days, additional justification from the PI is required to be attached to the journal entry.

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XIII. INDIRECT COSTS

POLICY: Indirect costs and their related distribution formulae for all grants, contracts, and sponsored projects will be negotiated by the Principal Investigator (PI)/Project Director and the Office of Grants and Sponsored Projects at the time that the proposal is submitted. In the cases of those already received by the University, the current policy or a precedent approved by the Provost and President will apply. The indirect amount will be included on Lesley's grant submission checklist.

PROCEDURE: The indirect amount is established according to the Award Set-Up Policy and Procedure for establishing any new account at the University. When the grant award letter is received in the Finance Office, revenue accounts will be set up at the same time that the grant budget is established. These revenue accounts will be used to allocate revenue from the grants indirect costs. The allocations will be distributed by percent based on the criteria outlined below. The indirect cost revenue will be allocated as the expenditures occur and may not be available at the beginning of the grant period.

The following scenarios exemplify how indirect costs are redistributed:

1. When the Principal Investigator is also a director of a center or institute,
 - a. an account will be established in the name of the project and will be given 10% of the indirect cost revenue for the PI's use;
 - b. the department/school/center/institute account will receive 20% to support faculty research projects; and,
 - c. the Office of Sponsored Projects account will receive 70% for grants management.
2. When the Principal Investigator is a "contractor" or an "administrator," the percent allocation to be applied may vary and shall be determined at the time of the proposal submission by the Provost, Vice President for Academic Affairs.

The accounts to which the indirect costs will be distributed will be set by the Finance Office for each Principal Investigator/Project Director, for the departments and for the Division of Academic Affairs. The signature authorities for the Principal Investigators'/Project Directors' accounts will be the Principal Investigator/Project Director and her/his dean or unit head/Vice President. The signature authorities for the department chairs' accounts will be the department chair and her/his school dean or Vice President.

The funds will be distributed quarterly (January, April, July, and October), effective July 1, 2011, and may be used for expenses such as travel to professional conferences, research materials and equipment, and other approved expenditures for research and scholarly activities. All such funds will not be able to be "rolled" from one fiscal year to the next.

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XIV. EXPORT CONTROLS

Office of Grants and Sponsored Projects, Compliance with Export Control Regulations

INTRODUCTION:

Over the past few years the Federal government has become increasingly involved with protecting information and technology from disclosure by universities, the release of which could hamper U.S. economic vitality or contributes to the military personnel of the U.S. international adversaries. Export laws and regulations promulgated by the U.S. Department of Commerce, the U.S. Department of State and the Treasury Department's Office of Foreign Assets Control are the bases for restricting use and access to this information and technology. These laws impact research, foreign travel and the transfer of technology and information to certain countries. The laws also impose severe criminal and civil fines for noncompliance. It is important that all persons involved in sponsored research understand the regulations and implementation requirements.

This information sheet provides an overview of the Department of Commerce's ITAR and EAR regulations, the Office of Foreign Assets Control embargoes, principal investigator responsibilities, examples for LU faculty and staff, penalties for non-compliance and important links for further information.

OVERVIEW OF 'ITAR' AND 'EAR':

Export Control is regulated by the Department of Commerce's Export Administration Regulations (EAR) and by International Traffic in Arms Regulations (ITAR). These regulations control the export of commodities, software, technical data, and information to foreign countries.

Export commonly refers to the shipment or transmission of items, services, or technical data out of the United States. However, under EAR and ITAR export can also refer to the release of technology or software technical data to a foreign national in the United States (deemed export). Software or technical data is considered released for export through:

- visual inspection by foreign nationals of equipment and facilities that originated in the United States;
- oral exchanges of information in the United States and abroad; or,
- the application to situations abroad of personal knowledge or the experience acquired in the United States.

EAR uses the regulations in the Commerce Control List maintained by the Bureau of Industry and Security (BIS) that includes items, commodities, software, and technology subject to the authority of BIS. ITAR regulations focus on the export of defense articles and defense services and use a list of categories called the U.S. Munitions List.

ITAR and EAR cover items of U.S. origin, such as:

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- equipment
- chemicals
- biological substances
- other materials
- software code
- computers

ITAR and EAR issues usually do not pertain when your research and the information you are working with:

- is in the public domain
- is not encrypted software
- does not have sponsor restrictions on publication; and/or
- is not related to space or missile technologies, military technologies, or military applications.

An export license may be required before a controlled item or material may be exported. A license could take 3-6 months to acquire. For example, you cannot ship computers to restricted countries without licenses. There are severe penalties for non-compliance.

THE OFFICE OF FOREIGN ASSETS CONTROL:

In addition to ITAR and EAR, the Office of Foreign Assets Control (OFAC) of the U.S. Department of the Treasury administers and enforces economic and trade sanctions based on U.S. foreign policy and national security goals against targeted foreign countries, terrorists, international narcotics traffickers, and those engaged in activities related to the proliferation of weapons of mass destruction. OFAC prohibits payments or providing anything of value to sanctioned countries, nationals of some countries and specified entities.

OFAC also prohibits travel to and other activities with embargoed countries and entities. *In general, OFAC "trumps" export controls.* The countries where U.S. policy is normally to deny licenses is: Afghanistan, Belarus, Cuba, Iran, Iraq, Libya, North Korea, Syria, Vietnam and to countries where the U.S. has an arms embargo (Burma, China, Haiti, Liberia, Rwanda, Somalia, Sudan, Zaire) and in certain circumstances also Armenia and Azerbaijan.

PRINCIPAL INVESTIGATOR RESPONSIBILITIES:

Every principal investigator should ask him/herself the following questions:

- Does the research involve any EAR categories?
- Does the research involve any item on the ITAR munitions list?
- Does the research involve technology or devices designed for use in military, security, and intelligence applications?
- Does the research involve anything else with a substantial or dual-use military application?

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- Will you collaborate in any way with a foreign national as a research or commercial partner?
- Will you use a research assistant who is a foreign national?
- Will you send your research results to a foreign country or foreign citizens?
- Do you anticipate any foreign travel associated with the project?

If you answer affirmatively to *any* of these questions, then there is a possibility that export control does apply to your project. You must consult with the Office of Sponsored Projects to determine if export controls pertain to your project and if a license is required.

Examples when export controls may apply to a LU employee:

- A LU employee carries a laptop computer into one of the OFAC/embargoed countries.
- A LU employee carries a cellular phone that has a GPS system into a restricted country.
- A LU employee accepts an award from the U.S. government that has propriety restrictions on the release of data.
- A LU employee ships computers or encrypted software to a foreign country.
- A LU employee collaborates with a foreign national or releases information to a foreign national on a research project for the federal government.

PENALTIES FOR NON-COMPLIANCE:

Faculty members are criminally liable for violating the ITAR/EAR/OFAC export controls or embargo's.

ITAR PENALTIES

- Criminal: up to \$1 million per violation and up to 10 years in prison
- Civil: seizure and forfeiture of articles, revocation of exporting privileges, fines of up to \$500,000 per violation.

EAR PENALTIES

- Criminal: \$50K-\$1million or five times the value of export, whichever is greater, per violation, or 10 years in prison.
- Civil: loss of export privileges, fines \$10K-\$120K per violation

OFAC PENALTIES

- Criminal: Up to \$1 million and 10 years in jail
- Civil: \$12K-\$55K per instance

IMPORTANT LINKS FOR FURTHER INFORMATION:

ITAR http://pmddtc.state.gov/regulations_laws/itar_official.html

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COMMERCE CONTROL LIST <http://www.access.gpo.gov/bis/>

US MUNITIONS LIST http://www.pmdtc.state.gov/regulations_laws/itar_consolidated.html

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XV. COST SHARING OR MATCHING

Generally, the University needs to carefully consider grants that require cost sharing. Any cost sharing commitment must be included on the Preliminary Grant Approval Form and in the proposed budget. The responsible University officials must identify the source of institutional funds and approve the cost sharing commitment on Lesley's Preliminary Grant Approval Form. Any committed cost sharing must be documented within the University's financial system. It is the policy of Lesley University that cost sharing or matching will be provided only when it is required or encouraged in the funding opportunity announcement.

Cost sharing is defined as institutional support of a share of the total cost of a project. An example of 50% cost sharing on a project with a total cost of \$100,000 is the institution must pay \$50,000 and the sponsor will pay \$50,000 to cover the total costs of \$100,000.

Matching is defined as sponsor required matching of funds in support of a project. An example of a 50% match of \$100,000 proposed request to a sponsor would require the institution to match \$50,000 to amount to total costs of \$150,000.

CRITERIA FOR COST SHARE OR MATCH

To be acceptable for use as cost sharing or matching, an expenditure must satisfy the following criteria:

- Be verifiable from official University records;
- Not be used as cost sharing for any other sponsored program;
- Be necessary and reasonable for proper and efficient accomplishment of project objectives;
- Be allowable under the applicable cost principles, OMB Circular Act A-21;
- Be itemized in the approved budget; and,
- Be incurred during the effective dates of the grant or contract.

ACCEPTABLE EXPENDITURES

In general, costs normally treated as direct costs on sponsored projects may be used to meet a cost sharing or matching obligation. Costs normally treated as indirect on sponsored projects may not.

A. Examples of expenditures that may be used as cost sharing or matching:

1. Faculty, staff, or student salaries and applicable fringe benefits
2. Laboratory supplies
3. Travel

B. Examples of expenditures that may not be used as cost sharing or matching:

1. Expenditures normally treated as indirect costs, such as administrative salaries and office supplies
2. Unallowable costs, such as alcoholic beverages, entertainment, and memberships in community organizations

SOURCES OF COST SHARE OR MATCH

Cost sharing or matching may be met from the following sources:

- University funds may be used as cost share or match when they are provided for the benefit of the specific project.

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- Waived indirect costs that are otherwise available to be recovered may be used as cost share or match if the University has agreed to accept less than the full amount. The difference between the indirect costs accepted and the amount that would have been provided at the full rate may be used as cost sharing or matching if approved by the sponsor.
- Unfunded indirect costs may be used as cost share or match when the sponsor does not reimburse indirect costs at the full rate due to sponsor policy, government legislation, or terms of the agreement. If the difference is to be used as cost share or match, it must be approved by the sponsor.
- In exceptional circumstances, another sponsored project account may be used as cost share or match if approved in advance by both sponsors. Note that federal funds may not be used as cost sharing or matching on other federally-sponsored projects.
- Third-party contributions (support from a non-University source) may be used as cost share or match if committed in writing by the third party.

OMB Circular A-21 also provides specific rules for valuation and documentation of volunteer services, donated supplies, property buildings, and equipment. In general, however, it is the University's preference to avoid referring to these items as cost share or match and characterize them instead as "available for the use of the project at no direct cost."

COST SHARING OR MATCHING OBLIGATION

There are several points in the proposal and award process at which the University may incur a cost sharing or matching obligation. Cost sharing or matching may be committed in the proposal to the sponsor for one of the following reasons: the sponsor (or a particular program of the sponsor) requires cost sharing or matching as a condition of applying for an award. In both of these situations, cost sharing or matching is quantified in the proposal budget and becomes a condition of the sponsor's award. These instances are normally referred to as mandatory or voluntarily committed cost sharing.

All types of cost sharing or matching obligations described above must be documented and identifiable in the University accounting system.

COST SHARE OR MATCH COMMITMENTS AT PROPOSAL STAGE

1. The project director shall secure required cost share or match commitments early in the proposal developmental stage and document appropriately in the proposal budget and narrative.
2. The project director shall secure written approval on the Proposal Summary Form from the individuals responsible for the organization code from which cost share or match is committed.
3. The department chair and dean (or equivalent supervisors in administrative units) shall review and sign the Preliminary Grant Approval Form to identify and approve any committed cost share or matches, then send the form to the Provost for approval.
4. OGSP shall review the proposal to identify any committed cost share from the University. If cost share or match is committed, OGSP shall ensure that appropriate cost share documentation has been included on the Preliminary Grant Approval Form,

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including the organization code for the cost share or match funds and written approval from the individual responsible for the organization code.

COST SHARE OR MATCH COMMITMENTS AT AWARD STAGE

1. If the award amount is less than the proposed budget, the department's budget personnel and/or OGSP shall work with the program director to determine whether the University has incurred a cost sharing or matching obligation beyond what was committed in the proposal. If additional cost share or match obligations are incurred at the award stage, written approval shall be obtained from the individuals responsible for the funds to be used as cost share or match.
2. OGSP, and/or the Advancement Grants Officer and the department's budget personnel, shall review award conditions and ensure that required cost share or match is committed and identified prior to acceptance of the award.
3. OGSP and/or the Advancement Grants Officer shall provide documentation of the award and a budget that identifies sponsor funding and cost share or match commitments to the Accountant in the Finance Office.

COST SHARE OR MATCH DOCUMENTATION AND REPORTING

1. The Accountant in the Finance Office shall establish a companion cost sharing or matching account for all awarded projects with committed cost share or match.
2. The Project Director shall provide accurate source documentation for all cost sharing or matching expenses on awarded projects to the Accountant in the Finance Office.
3. The Accountant in the Finance Office shall monitor expenditures from the cost sharing or matching account as well as from the grant/contract account and report cost share or match expenditures according to the sponsor's award terms and billing instructions.

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XVI. INTELLECTUAL PROPERTY

Intellectual Property Policy for Sponsor-Supported Efforts of Faculty and Librarians
Lesley University

PREAMBLE

Lesley University, hereinafter referred to as "LU," is dedicated to teaching, research, and the extension of knowledge to the public. LU recognizes and encourages the production and publication of scholarly works and research as an integral part of the process of teaching, research, and service. Inventions and materials, including the development of new and useful materials, software, devices, processes, and other inventions, some of which may have potential for commercialization, and which qualify for patent or copyright protection, may come about through the activities of LU faculty and librarians who have been aided wholly or in part through external funding awarded to LU. LU therefore establishes this Intellectual Property Policy that is consistent with the Memorandum of Agreement of April 25, 2003 between the Massachusetts Board of Higher Education and the Massachusetts Teachers Association acting through the Massachusetts State College Association (the "Memorandum of Agreement").

Intellectual Property, for the purpose of this policy, is defined as creative and scholarly works and inventions that may be protected under the laws of various countries that establish rights called "Intellectual Property." This term includes patents, copyrights, trade secrets, trademarks, plant variety production and other rights (definitions are included in Section V) and includes "intellectual property" within the meaning of the Memorandum of Agreement, which states that " 'intellectual property' shall mean a legally cognizable interest in a work or creation of whatever kind, including a copyright or patent."

I. POLICY STATEMENT

It is the policy of LU that copyrights, patents, and all other Intellectual Property rights arising from aesthetic, scholarly, or other research, when developed through independent efforts and not as part of a directed institutional assignment, shall reside with the originator unless LU and the originator have otherwise agreed or unless the terms of a grant external to LU and the System otherwise provide. Independent effort is defined as the product of inquiry, investigation, creative activity or research where the specific choice, content, course, and direction of the effort are determined by the individual without assignment or supervision by the institution or System. Every faculty member and librarian is therefore entitled to own and hold the rights to intellectual property that he or she creates in any book, monograph, academic paper, article, course materials (within the meaning of the Memorandum of Agreement), musical composition, work of art, dissertation, thesis software program, or like material, but this entitlement is subject to any agreement made with LU or the requirements of any external grant.

LU owns and holds the rights to intellectual property in anything created for it and at its direction (including any specific assignment or when it provides specific resources to develop the intellectual property) unless, as a matter of law, this Policy, any agreement or the terms of any external grant, they reside elsewhere. Assignment, supervision, or resource support that is

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customary for research and instructional purposes does not establish an interest by LU or the System in resultant intellectual property. Unless otherwise agreed, this Policy also applies to any intellectual property in which LU has an interest under the terms of contracts, grants, or otherwise. Any intellectual property in which LU does not have a legal interest may be offered to LU and, if accepted, LU will administer such intellectual property in accordance with this Intellectual Property Policy or as otherwise agreed.

The President of Lesley University, by virtue of authority granted by the Board of Trustees, shall, in conformity with this Policy, manage and oversee all Intellectual Property that is or may become, in whole or in part, the property of LU, and he may further allocate or dispose of LU's rights in such Intellectual Property in such fashion as he judges is in the best interests of LU.

Occasionally, LU may enter into separate contractual agreements with personnel, such as, but not limited to, consulting, sabbatical, and in-residence agreements that benefit LU. The Intellectual Property Policy will not supersede those instances of separate contractual agreements between personnel and LU.

Regarding educational fair use and copyright issues, LU personnel must adhere to established LU copyright policy and applicable provisions of law.

II. RIGHTS AND EQUITIES IN INTELLECTUAL PROPERTY

II.A. Ownership by Category of Work

II.A.1. *Scholarly/Aesthetic Works:* In keeping with traditional academic practice and policy, ownership of copyrights, patents or trademarks to scholarly or aesthetic works that are prepared through individual effort and not as part of a directed assignment shall reside with the originator except as otherwise provided in this Policy. The general practice of faculty (including librarians) to produce scholarly works does not constitute a directed assignment, and nothing in this policy shall be deemed to alter or abridge the rights to intellectual property conferred on faculty and librarians by the Memorandum of Agreement.

II.A.2. *Works Created by Individual Effort:* The copyrights, patents, or trademarks to any work that is prepared outside the scope of an employee's employment at LU and without his or her use of LU's or the System's resources shall be the property of the employee. *However*, LU asserts its rights to sponsored works and contracted works shall be governed by the sponsorship agreements or applicable contracts.

II.A.3. *Commissioned Works:* When LU commissions the production of a work, title to the Intellectual Property in it will normally reside with LU. In all cases, copyright, patent, or trademark ownership shall be specified in the written contract or other writing detailing the terms of the commission.

II.A.4. *Works Acquired by Assignment, Gift, or Will:* If accepted by the President acting as designee of the Board of Trustees, LU may acquire works, including the Intellectual

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Property rights therein, by assignment, gift or bequest; and all such works and rights shall be held, applied and disposed of pursuant to the terms of the instrument governing the same and otherwise as the President judges is in the best interest of LU.

II.B. Sponsor-Supported Efforts:

Sponsored projects, including sponsored research, shall be governed by agreements between LU (or the System) and the persons (including employees) who are engaged in the project. Those sponsored-project agreements must contain specific provisions with respect to the ownership of any Intellectual Property developed during the course of the project, in which case the terms of the sponsored project agreement shall establish ownership. When the sponsored project agreement is silent on the matter, all rights in any such Intellectual Policy shall vest in LU unless the provisions of this Policy, exclusive of this provision, otherwise provide (also see Memorandum of Agreement, April 25, 2003, Article III.B (12) (a)(b)(c)).

Income, if any, from such Intellectual Property shall be shared, subject to the sponsor's requirements, in accordance with Section III.H.

III. ADMINISTRATIVE PROCEDURES

III.A. Responsibility

The administration of the principles and policies set forth in this document is the responsibility of the Provost and Vice President for Academic Affairs, whose office shall do so through the LU Office of Sponsored Projects with the advice of the LU Intellectual Property Advisory Board (the "IPAB"). The IPAB shall be appointed by the President and the MSCA, and consist of no fewer than three and no more than nine members, one of whom shall be designated by the President to serve as Chair. Additional *ad hoc* members may be added by the Chair at any time as considered necessary.

III.B. Disclosure of Intellectual Property

LU personnel will promptly disclose to the Provost and Vice President for Academic Affairs, through the Office of Sponsored Projects, any works, new material, devices, processes, or other inventions or creations which, by the terms of this Policy (including any agreements made in accordance with this Policy), LU owns or in which by such terms it has a right to any Intellectual Property. A disclosure form will be provided for this purpose by the Provost and Vice President for Academic Affairs. LU personnel shall also cooperate by signing all papers deemed necessary to protect and/or to commercialize any such Intellectual Property.

III.C. Confidentiality

Certain contractual obligations and governmental regulations (including, in the case of LU employees, the State Ethics Statute) require that information be maintained in confidence. Additionally, some works, such as certain computer software, may best be protected and licensed as trade secrets, and inventions must be maintained in confidence for limited

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periods to avoid the loss of patent rights. Accordingly, the timing of publications and other disclosures is important, and LU personnel shall use their best efforts to keep the following items confidential:

- (1) All information or material designated confidential in a contract, grant, or the like;
- (2) All information or material designated or required to be maintained as confidential under any applicable governmental statutes or regulations; and,
- (3) All information relating to Intellectual Property developed by LU employees in whom LU may have an interest under this Policy until application has been made for protection or LU has declined to make such application.

III.D. Collaboration

Collaboration between LU employees and persons not employed or associated with LU, including researchers at other universities or companies can result in the development of Intellectual Property jointly owned by LU, its employees and other persons or their employers. Protection and Commercialization of such joint Intellectual Property can be difficult without extensive cooperation and agreement among the owners. LU employees involved in or contemplating collaborative activities that may result in the development of Intellectual Property in which LU may have an interest will advise LU of such activities.

III.E. Administration of Commissioned and Sponsor-Supported Efforts

The IPAB has the responsibility to evaluate Intellectual Property developed from Commissioned- and Sponsor-Supported Efforts and to recommend to the President or her/his designee whether to administer such Intellectual Property by undertaking such efforts as he or she determines, in his or her sole discretion, to be appropriate to protect and license or otherwise commercialize such Intellectual Property.

III.F. Disposition of Certain Intellectual Property

Whenever LU chooses not to exercise or exploit its interest in Intellectual Property or chooses to cease to do so, then LU, subject to its obligations to any sponsor and to the requirements of any agreement or other governing instrument, may assign such interest to the originator to dispose of as the originator sees fit or may otherwise dispose of it as LU sees it. Decisions of the kind described here might be made the subject of deliberations by the IPAB but shall be finally made by the President or her/his designee.

III.G. Revenue Sharing with Originators of Commissioned and Sponsor-Supported Efforts

In the cases of Commissioned- and Sponsor-Supported Efforts, the division of Net Revenue generated from Intellectual Property administered by LU shall be distributed in accordance with individual agreements made between LU, the originator and any other parties as required by the funding source.

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The originator's share of Net Revenue shall be divided (equally) among joint originators of jointly developed Intellectual Property unless a written statement signed by all joint originators which provides for a different distribution is filed with LU prior to the first distribution of shared net revenue.

If the originator is no longer an employee of LU, this share is returned to Administration for redistribution, unless any applicable agreement, grant, or other instrument otherwise provides. In the event the terms under which any Intellectual Property is licensed, sold, or otherwise exploited provide LU with equity, or an option to acquire equity, in the entity which exploits the Intellectual Property, the share of such equity due to originators as identified above will be distributed to the originators when such equity is transferable or convertible to cash and otherwise in accordance with any applicable agreement or other governing instrument.

III.H. Interpretation, Decision, and Appeal

Cases where the originator and LU agree as to the classification and proposed mechanism of commercialism of the Intellectual Property will be processed by LU in accordance with this Policy. All cases in which questions arise as to equities, rights, division of royalties, or any other Intellectual Property-related manner shall be referred to the IPAB for consideration, interpretation of policy, and decision. Appeal of an IPAB decision shall be sent to the Provost and Vice President for Academic Affairs, then to the President, and, finally, to the Board of Trustees. Appeals within LU must be made in writing within sixty (60) days of written notice of a final decision. Appeals to the Board of Trustees shall be filed within twenty (20) days of the final decision of the LU President.

IV. PREVAILING POLICY: HEIRS AND ASSIGNS

IV.A. Prevailing Policy

In the event of conflicts between the Intellectual Property Policy of Lesley University and the provisions of any collective bargaining agreement, the provision of the latter shall prevail.

IV.B. Heirs and Assigns

The provisions of this Policy shall inure to the benefit of and be binding upon the successors, heirs and assigns of (1) LU; (2) all LU employees and students; and (3) all others who agree to be bound by it.

V. DEFINITIONS

- *Intellectual Property* shall be deemed to copyrighted materials, patentable materials, software, trademarks, and trade secrets, whether or not formal protection is sought.
- *Course Materials* shall mean lectures, exercises designed for online collaboration, multimedia developed for web distribution, notes, outlines, syllabi, bibliographies, tests, instructional handouts, videotaped presentations and any like materials and documents (whether in an electronic or other medium) that a member of the faculty and librarian

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bargaining unit authors or creates in connection with the preparation or teaching of a course (per Memorandum of Agreement, April 25, 2003).

- *Copyrighted Materials* shall include the following: (1) literary works; (2) musical works, including any accompanying words; (3) dramatic works, including any accompanying music; (4) pantomimes and choreographic works; (5) pictorial, graphic and sculptural works; (6) motion pictures and other audiovisual works; (7) sound recordings; (8) architectural works; and (9) computer software.

The following are not protected by copyright: (1) works that have not been fixed in a tangible form of expression; written, recorded, or captured electronically; (2) titles, names, short phrases, and slogans; familiar symbols or designs; mere variations of typographic ornamentation, lettering or coloring; mere listings of ingredients or contents; (3) ideas, procedures, methods, systems, processes, concepts, principles, discoveries or devices, as distinguished from a description, explanation, or illustration; (4) works consisting entirely of information that are natural or self-evident facts, containing no original authorship, such as the white pages of telephone books, standard calendars, height and weight charts and tape measures and rulers; (5) works created by the U.S. government; (6) works for which copyright has expired; and (7), works in a public domain. (Source: <http://www.copyright.com>)

- *Mask Work* means a series of related images, however fixed or encoded: having or representing the predetermined, three dimensional pattern of metallic, insulating, or semiconductor material present or removed from layers of a semiconductor chip product; and in which series the relation of the images to one another is that each image has the pattern of the surface of one form of the semiconductor chip product.
- *Net Revenue* means gross receipts received by LU from license activity minus the costs incurred by LU in protecting, licensing, marketing and distributing the Intellectual Property.
- *Novel Plant Variety* means a novel variety of a sexually reproduced plant.
- *Patentable Materials* shall be deemed to refer to items other than software which reasonably appear to qualify for protection under the patent laws of the United States or other protective statutes, including Novel Plant Varieties and Patentable Plants, whether or not patentable there under.
- *Patentable Plant* means an asexually reproduced distinct and new variety of plant.
- *Software* includes one or more computer programs existing in any form, or any associated operational procedures, manuals or other documentation, whether or not protectable or protected by patent or copyright. The term "computer program" shall mean a set of instructions, statements, or related data that, in actual or modified form, is capable of causing a computer or computer system to perform specified functions.
- *Trademarks* shall include all trademarks, service marks, trade name, seals, symbols, designs, slogans, or logotypes developed by or associated with LU or any of its institutions.
- *Trade Secrets* means information including, but not limited to, technical or nontechnical data, a formula, a pattern, a compilation, a program, a device, a method, a technique, a drawing, a process, financial data, financial plans, product plans, or a list of actual or potential customers or suppliers which: derive economic value, actual or potential from

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not being generally known to, and not being readily ascertainable through proper means by, other persons who can obtain economic value from its disclosure or use; and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Further information can be found at: <http://lesley.edu/provost/copyright.html>.

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XVII. CLOSE-OUT PROCEDURE

In order to facilitate the capture of all direct and indirect costs associated with an award or contract, Lesley has initiated the following process.

At 90 days prior to the termination date of the award or contract, the PI will receive an email indicating that the 90 day threshold has been reached. The department budget coordinator will ask if the program and its related expenditures are on track and request that the PI review the status of the award. The department budget coordinator will offer to request a no cost extension or any necessary budget modification from the sponsor on behalf of the PI.

At 60 days prior to the termination date, the PI will receive another email from the department budget coordinator stating that they are at 60 days out from their termination and requesting that the PI review the fiscal and programmatic status of their account. They should be looking for expenditures which have not yet hit the grant that should have and ensure that all expenditures that have hit the grant are appropriate. In addition, the PI will be asked to review their purchasing needs and complete them before the month's end.

At 30 days prior to the term date, the PI will receive a final notice from the budget coordinator indicating that with exceptions and excluding payroll, no further expenses will be allowed to be processed on the account. This step is in place to ensure that the University is able to capture all costs associated with the award or contract and to avoid audit findings later as large, unjustified expending during the final month of a grant are red flags for auditors.

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XVIII. NIH PubMed CENTRAL POLICY

All Lesley University NIH Principal Investigators are required to ensure that publications derived from research funded by the National Institute of Health (NIH) will be submitted to PubMed Central. According to the NIH, "Authors should work with the publisher before any rights are transferred to ensure that all conditions of the NIH Public Access Policy can be met. Authors should avoid signing any agreements with publishers that do not allow the author to comply with the NIH Public Access Policy." The PI should disclose to the publisher upon submission of an article that it is subject to this NIH policy. The journal's author instructions and copyright transfer or publication agreement should be reviewed for any language that may prohibit the PI from complying with submission to PubMed Central. Specific language should appear in the copyright transfer or publication agreement specifically allowing for deposit PMC.

If it does not, an addendum should be attached to the agreement by the PI. NIH recommended language is as follows: "Journal acknowledges that Author retains the right to provide a copy of the final manuscript to the NIH upon acceptance for Journal publication, for public archiving in PubMed Central as soon as possible but no later than 12 months after publication by the Journal." Decisions about the approved submission will need to be negotiated with the Publisher. Should the PI require assistance with these negotiations, the Office of Sponsored Projects will be happy to assist.

PI's have four methods appropriate and consistent with the NIH publishing agreement:

1. Publish in a journal that deposits all NIH-funded final published articles in PMC without author involvement.
2. Make arrangements to have a publisher deposit a specific final published article in PMC.
3. Deposit the final peer-reviewed manuscript in PMC yourself via the NIH Manuscript Submission System (NIHMS).
4. Complete the submission process for a final peer reviewed manuscript that the published has deposited via the NIHMS: http://publicaccess.nih.gov/submit_process.htm.

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XIX. NSF PROJECT OUTCOMES REPORT REQUIREMENT

"Required in awards made on/after January 2010, the Outcomes Report must be submitted electronically via Research.gov within 90 days of the expiration of the grants. The report is a brief summary prepared specifically for the public, describing the nature and outcomes of the project within the context of NSF's review criteria- the intellectual merit and/or broader impacts of the work-written for the lay reader. NSF will automatically attach all publications resulting from an award as reported annually in the FastLane Project reporting system to the Outcomes Report. The Project Outcomes Report Address [is] a requirement included in the America COMPETES Act of 2007 (PL 110-69)." "This requirement is met by the investigator, but is a term/condition of an award."

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XX. Drug-Free Workplace Statement

It is the intent of the Administration of Lesley University to make a good-faith effort to provide a drug-free workplace for its regular and student employees both in terms of procedure and results. To this end, the unlawful manufacture, distribution, dispensation, possession or use of a controlled substance is prohibited in the workplace of Lesley University. Any employee of Lesley University who is convicted on a violation of this principle, will be subject to an appropriate measure of discipline that could result in termination of his/her employment with the University. As a condition of employment, all employees must abide by the terms of this statement and report to the Director of Human Resources any conviction under a criminal drug statute for conduct in the workplace no later than five days after the conviction. Any employee so convicted, and who is not terminated from employment, may be required to participate satisfactorily in a drug-abuse assistance or rehabilitation program acceptable to the University Administration as a continuation of employment. In keeping with the intent of the Drug-Free Workplace Act, Lesley University will continue an on-going drug awareness program that will be made available to all employees who directly engage in work under the provisions of a grant or contract. A copy of this statement will be provided to all employees working under the Federal contract or grant.

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XXI. The Massachusetts Whistleblower Protection Act

THE MASSACHUSETTS WHISTLEBLOWER PROTECTION ACT "An Act to Protect Conscientious Employees"

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows: Chapter 149 of the General Laws, as appearing in the 1992 Official edition, is hereby amended by inserting after section 184 the following:

SECTION 185

(a) As used in this section, the following words shall have the following meanings:

- (1) "Employee", any individual who performs services for and under the control and direction of an employer for wages or other remuneration.
- (2) "Employer", the commonwealth, and its agencies or subdivisions, including, but not limited to, cities, towns, counties and regional school districts, or any authority, commission, board or instrumentality thereof.
- (3) "Public body",
 - (a) the United States Congress, any state legislature, including the general court, or any popularly elected local government body, or any member or employee thereof;
 - (b) any federal, state, or local judiciary, or any member or employee thereof, or any grand or petit jury;
 - (c) any federal, state, or local law enforcement agency, prosecutorial office, or police or peace officer; or,
 - (d) any division, board, bureau, office, committee, or commission of any of the public bodies described in the above paragraphs of this subsection.
- (4) "Supervisor", any individual to whom an employer has given the authority to direct and control the work performance of the affected employee, who has the authority to take corrective action regarding the violation of the law, rule or regulation of which the employee complains, or who has been designated by the employer on the notice required under subsection (g).
- (5) "Retaliatory action", the discharge, suspension or demotion of an employee, or other adverse employment action taken against an employee in the terms and conditions of employment.

(b) An employer shall not take any retaliatory action against an employee because the employee does any of the following:

- (1) Discloses, or threatens to disclose to a supervisor or to a public body an activity, policy or practice of the employer, or of another employer with whom the employee's employer has a business relationship, that the employee reasonably believes is in violation of the law, or rule or regulation promulgated pursuant to law, or which the employee reasonably believes poses a risk to public health, safety, or the environment;
- (2) Provides information to, or testifies before, any public body conducting an investigation, hearing or inquiry into any violation of law, or a rule or regulation promulgated pursuant to law, or activity, policy or practice which the employee reasonably believes poses a risk to public health, safety or the environment by the

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employer, or by another employer with whom the employee's employer has a business relationship; or

(3) Objects to, or refuses to participate in any activity, policy or practice which the employee reasonably believes poses a risk to public health, safety, or the environment.

(1) Except as provided in paragraph (2), the protection against retaliatory action provided by subsection (b)(1) shall not apply to an employee who makes a disclosure to a public body unless the employee has brought the activity, policy or practice in violation of the law, or a rule or regulation promulgated pursuant to law, or which the employee reasonably believes poses a risk to public health, safety or the environment, to the attention of a supervisor of the employee by written notice and has afforded the employer a reasonable opportunity to correct the activity, policy or practice.

(2) An employee is not required to comply with paragraph (1) if he:

(A) is reasonably certain that the activity, policy or practice is known to one or more supervisors of the employer and the situation is emergency in nature;

(B) reasonably fears physical harm as a result of the disclosure provided; or

(C) makes the disclosure to a public body as defined in clause (B) or (D) of the definition of 'public body' in subsection (a) for the purpose of providing evidence of what the employee reasonably believes to be a crime.

(c) [No subsection c]

(d) Any employee or former employee aggrieved by a violation of this section may, within two years, institute a civil action in the superior court. Any party to said action shall be entitled to claim a jury trial. All remedies available in common law tort actions shall be made available to prevailing plaintiffs. These remedies available in common tort law actions shall be made available to prevailing plaintiffs. These remedies are in addition to any legal or equitable relief provided herein. The court may:

(1) issue temporary restraining orders or preliminary or permanent injunctions to restrain continued violation of this section;

(2) reinstate the employee to the same position held before the retaliatory action, or to an equivalent position;

(3) reinstate full fringe benefits and seniority rights to the employee;

(4) compensate the employee for three times the lost wages, benefits and other remuneration, and interest therein; and

(5) order payment by the employer of reasonable costs, and attorney's fees.

(1) Except as provided in paragraph (2), in any action brought by an employee under subsection (d), if the court finds the action was without basis in law or fact, the court may award reasonable attorney's fees and court costs to the employer.

(2) An employee shall not be assessed attorney's fees under paragraph (1) is, after exercising reasonable and diligent efforts after filing a suit, the employee moves to dismiss the action against the employer, or files a notice agreeing to a voluntary dismissal, within a reasonable time after determining that the employer would not be found liable for damages.

(e) [No subsection e]

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(f) Nothing in this section shall be deemed to diminish the rights, privileges or remedies of any employee under any other federal or state law or regulation, or under any collective bargaining agreement or employment contract; except that the institution of a private action in accordance subsection (d) shall be deemed a waiver by the plaintiff of the rights and remedies available to him, for the actions of the employer, under any other contract, collective bargaining agreement, state law, rule or regulation, or under common law.

(g) An employer shall conspicuously display notices reasonably designed to inform its employees of their protection and obligations under this section, and use other appropriate means to keep its employees informed. Each notice posted pursuant to this subsection shall include the name of the person or persons the employer has designated to receive written notification pursuant to subsection (c).

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XXII. LESLEY UNIVERSITY SMOKING POLICY

- **PART IV CRIMES, PUNISHMENTS AND PROCEEDINGS IN CRIMINAL CASES**
(Chapters 263 through 280)
 - **TITLE I CRIMES AND PUNISHMENTS**
 - **CHAPTER 270 CRIMES AGAINST PUBLIC HEALTH**
 - **Section 22** Smoking in public places

SECTION 22. (a) As used in this section, the following words shall have the following meanings, unless the context requires otherwise:

"Business agent", an individual who has been designated by the owner or operator of any establishment to be the manager or otherwise in charge of the establishment.

"Compensation", money, gratuity, privilege, or benefit received from an employer in return for work performed or services rendered.

"Customer service area", an area of the workplace that a business invitee may access.

"Employee", an individual or person who performs a service for compensation for an employer at the employer's workplace, including a contract employee, temporary employee, and independent contractor who performs a service in the employer's workplace for more than a *de minimis* amount of time.

"Enclosed", a space bounded by walls, with or without windows or fenestrations, continuous from floor to ceiling and enclosed by 1 or more doors, including but not limited to an office, function room or hallway.

"Lodging home", a dwelling or part thereof which contains 1 or more rooming units in which space is let or sublet for compensation by the owner or operator to 4 or more persons. The residential portion of boarding houses, rooming houses, dormitories, and other similar dwelling places are included in this definition. Hospitals, sanitariums, jails, houses of correction, homeless shelters, and assisted living homes are not included in this definition.

"Membership association", a not-for-profit entity that has been established and operates, for a charitable, philanthropic, civic, social, benevolent, educational, religious, athletic, recreation or similar purpose, and is comprised of members who collectively belong to:

- (i) a society, organization or association of a fraternal nature that operates under the lodge system, and having 1 or more affiliated chapters or branches incorporated in any state; or
- (ii) a corporation organized under chapter 180; or
- (iii) an established religious place of worship or instruction in the commonwealth whose real or personal property is exempt from taxation; or
- (iv) a veterans' organization incorporated or chartered by the Congress of the United States, or otherwise, having 1 or more affiliated chapters or branches incorporated in any state.

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Except for a religious place of worship or instruction, an entity shall not be a membership association for the purposes of this definition, unless individual membership is required for all members of the association for a period of not less than 90 days.

"Outdoor space", an outdoor area, open to the air at all times and cannot be enclosed by a wall or side covering.

"Public building", a building owned by the commonwealth or any political subdivision thereof, or in an enclosed indoor space occupied by a state agency or department of the commonwealth which is located in a building not owned by the commonwealth.

"Public transportation conveyance", a vehicle or vessel used in mass public transportation or in the transportation of the public, including a train, passenger bus, school bus or other vehicle used to transport pupils, taxi, passenger ferry boat, water shuttle or other equipment used in public transportation owned by, or operated under the authority of the Massachusetts Bay Transportation Authority, the Woods Hole, Martha's Vineyard & Nantucket Steamship Authority, Massachusetts Port Authority; state transportation department; or a vehicle or vessel open to the public that is owned by, or operated under the authority of a business, including tour vehicles or vessels, enclosed ski lifts or trams, passenger buses or vans regularly used to transport customers. Notwithstanding the foregoing, a private vehicle or vessel not open to the public or not used for the transportation of the public during the times of use, including a private passenger vehicle, a private charter or rental of a limousine, bus or van or the private rental of a boat or other vessel, shall not be considered a public transportation conveyance.

"Residence", the part of a structure used as a dwelling including without limitation: a private home, townhouse, condominium, apartment, mobile home; vacation home, cabin or cottage; a residential unit in a governmental public housing facility; and the residential portions of a school, college or university dormitory or facility. A residential unit provided by an employer to an employee at a place of employment shall be considered to be a residence; if the unit is an enclosed indoor space used exclusively as a residence, and other employees, excluding family members of the employee, or the public, has no right of access to the residence. For the purposes of this definition, a hotel, motel, inn, lodge, bed and breakfast or other similar public accommodation, hospital, nursing home or assisted living facility shall not be considered a residence.

"Retail tobacco store", an establishment which is not required to possess a retail food permit whose primary purpose is to sell or offer for sale to consumers, but not for resale, tobacco products and paraphernalia, in which the sale of other products is merely incidental, and in which the entry of persons under the age of 18 is prohibited at all times, and maintains a valid permit for the retail sale of tobacco products as required to be issued by the appropriate authority in the city or town where the establishment is located.

"Smoking" or "smoke", the lighting of a cigar, cigarette, pipe or other tobacco product or possessing a lighted cigar, cigarette, pipe or other tobacco or non-tobacco product designed to be combusted and inhaled.

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"Smoking bar", an establishment that occupies exclusively an enclosed indoor space and that primarily is engaged in the retail sale of tobacco products for consumption by customers on the premises; derives revenue from the sale of food, alcohol or other beverages that is incidental to the sale of the tobacco products; prohibits entry to a person under the age of 18 years of age during the time when the business is open for business; prohibits any food or beverage not sold directly by the business to be consumed on the premises; maintains a valid permit for retail sale of tobacco products as required to be issued by the appropriate authority in the city or town where the establishment is located; and, maintains a valid permit to operate a smoking bar issued by the department of revenue.

"Workplace", an indoor area, structure or facility or a portion thereof, at which 1 or more employees perform a service for compensation for the employer, other enclosed spaces rented to or otherwise used by the public; and where the employer has the right or authority to exercise control over the space.

"Work space or work spaces", an enclosed area occupied by an employee during the course of his employment.

(b)(1) It shall be the responsibility of the employer to provide a smoke free environment for all employees working in an enclosed workspace.

(2) Smoking shall be prohibited in workplaces, work spaces, common work areas, classrooms, conference and meeting rooms, offices, elevators, hallways, medical facilities, cafeterias, employee lounges, staircases, restrooms, restaurants, cafes, coffee shops, food courts or concessions, supermarkets or retail food outlets, bars, taverns, or in a place where food or drink is sold to the public and consumed on the premise as part of a business required to collect state meals tax on the purchase; or in a train, airplane, theatre, concert hall, exhibition hall, convention center, auditorium, arena, or stadium open to the public; or in a school, college, university, museum, library, health care facility as defined in section 9C of chapter 112, group child care center, school age child care center, family child care center, school age day or overnight camp building, or on premises where activities are licensed under section 38 of chapter 10 or in or upon any public transportation conveyance or in any airport, train station, bus station, transportation passenger terminal, or enclosed outdoor platform.

(3) A person shall not smoke in the state house or in a public building or in a vehicle or vessel, owned, leased, or otherwise operated by the commonwealth or a political subdivision thereof, or in a space occupied by a state agency or department of the commonwealth which is located in another building, including a private office in a building or space mentioned in this sentence, or at an open meeting of a governmental body as defined in section 11A of chapter 30A, section 23A of chapter 39 and section 9F of chapter 34, or in a courtroom or courthouse. This subsection shall not apply to a resident or patient of a state hospital, the Soldier's Home in Massachusetts located in the city of Chelsea or the Soldier's Home in Holyoke.

(c) Notwithstanding subsection (b), smoking may be permitted in the following places and circumstances:

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(1) Private residences; except during such time when the residence is utilized as part of a business as a group childcare center, school age child care center, school age day or overnight camp, or a facility licensed by the department of early education and care or as a health care related office or facility;

(2)(i) premises occupied by a membership association, if the premises is owned, or under a written lease for a term of not less than 90 consecutive days, by the association during the time of the permitted activity if the premises are not located in a public building; but no smoking shall be permitted in an enclosed indoor space of a membership association during the time the space is:

(A) open to the public; or

(B) occupied by a non-member who is not an invited guest of a member or an employee or the association; or

(C) rented from the association for a fee or other agreement that compensates the association for the use of such space.

(ii) Smoking may be permitted in an enclosed indoor space of a membership association at all times, if the space is restricted by the association to admittance only of its members, the invited guest of a member, and the employees of the membership association. A person who is a contract employee, temporary employee, or independent contractor shall not be considered an employee of a membership association under this subsection. A person who is a member of an affiliated chapter or branch of a membership association that is fraternal in nature operating under the lodge system, and is visiting the affiliated association, shall be an invited guest for the purposes of this subsection.

(3) A guest room in a hotel, motel, inn, bed and breakfast or lodging home that is designed and normally used for sleeping and living purposes, that is rented to a guest and designated as a smoking room pursuant to paragraph (1) of subsection (g).

(4) A retail tobacco store, if the store maintains a valid permit for the sale of tobacco products issued by the appropriate authority in the city or town in which the retail tobacco store is located. All required permits shall be displayed in a conspicuous manner, visible at all times to patrons of the establishment.

(5) A smoking bar, if the smoking bar maintains a valid permit pursuant to this section. All required permits shall be displayed in a conspicuous manner, visible at all times to patrons of the establishment.

(6) By a theatrical performed upon a stage or in the course of a professional film production, if the smoking is part of a theatrical production, and if permission has been obtained from the appropriate local authority;

(7) By a person, organization or other entity that conducts medical or scientific research on tobacco products, if the research is conducted in an enclosed space not open to the public, in a laboratory facility at an accredited college or university, or in a professional testing laboratory as defined by regulation of the department of public health;

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(8) Religious ceremonies where smoking is part of the ritual; and

(9) A tobacco farmer, leaf dealer, manufacturer, importer, exporter, or wholesale distributor of tobacco products, may permit smoking in the workplace for the sole purpose of testing said tobacco for quality assurance purposes; if the smoking is necessary to conduct the test.

[There is no subsection (d).]

(e) If the outdoor space has a structure capable of being enclosed by walls or covers, regardless of the materials or the removable nature of the walls or covers, the space will be considered enclosed, when the walls or covers are in place. All outdoor spaces shall be physically separated from an enclosed work space. If doors, windows, sliding or folding windows or doors or other fenestrations form any part of the border to the outdoor space, the openings shall be closed to prevent the migration of smoke into the enclosed work space. If the windows, sliding or folding windows or doors or other fenestrations are opened or otherwise do not prevent the migration of smoke into the work space, the outdoor space shall be considered an extension of the enclosed work space and subject to this section.

(f)(1) A nursing home, licensed pursuant to section 71 of chapter 111 and any acute care substance abuse treatment center under the jurisdiction of the commonwealth, may apply to the local board of health having jurisdiction over the facility for designation of part of the facility as a residence.

(2) All applications shall designate the residential area of the facility. The residential area shall not contain an employee workspace, such as offices, restrooms or other areas used primarily by employees.

(3) The entire facility may not be designated as a residence.

(4) The designated residential area must be for the sole use of permanent residents of the facility. No temporary or short-term resident may reside in the residential portion of the facility.

(5) All areas in the designated residential area in which smoking is allowed shall be conspicuously designated as smoking areas and be adequately ventilated to prevent the migration of smoke to nonsmoking areas.

(6) The facility shall provide suitable documentation, acceptable to the local board of health, that the facility is the permanent domicile of the residents residing in that portion of the facility, that information on the hazards of smoking and second hand smoke have been provided to all residences and that smoking cessation aids are available to all residents who use tobacco products.

(7) The designated residential area shall be in conformance with the smoking restriction requirements of section 72X of chapter 111 and 105 CMR 150.015 (D)(11)(b). All residential

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areas shall be clearly designated as such and shall not be altered or otherwise changed without the express approval of the local board of health.

(8) All areas of a nursing home not designated as a residence hall shall comply with this section.

(9) The nursing home shall make responsible accommodations for an employee, resident or visitor who does not wish to be exposed to tobacco smoke.

(10) Upon compliance with this section, submission of the required documentation and satisfactory inspection, the local board of health shall certify the designated portion of the facility as a residence. The certification shall be valid for 1 year from the date of issuance. No fewer than 30 days before the expiration of the certification, the facility may apply for re-certification. If the local board of health does not renew the certification before its expiration or provide notice that it has found sufficient cause to not rectify the residence portion of the nursing home as such, the certification shall be considered to continue until the time as the local board of health notifies the nursing home of its certification status.

(g)(1) A designated smoking room in a hotel, motel, inn, bed and breakfast and lodging home shall be clearly marked as a designated smoking room on the exterior of all entrances from a public hallway and public spaces; and in the interior of the room. Instead of marking each room, an establishment may designate an entire floor of residential rooms as smoking. The floor shall be conspicuously designated as smoking at each entranceway on to the floor. Smoking shall not be allowed in the common areas of the floor, such as halls, vending areas, ice machine locations and exercise areas and shall comply with paragraph (4).

(2) A retail tobacco store that permits smoking on the premises shall, pursuant to paragraph (4), post in clear and conspicuous manner, a sign at each entrance warning persons entering the establishment that smoking may be present on the premises; of the health risks associated from second hand smoke; and, that persons under the age of 18 years of age may not enter the premises.

(3) A smoking bar shall, pursuant to paragraph (4), post in a clear and conspicuous manner signs at all entrances which warn persons entering the establishment that smoking may be present on the premises; and, of the health risks associated from second hand smoke; and, that persons under the age of 18 years of age may not enter the premises.

(4) Every area in which smoking is prohibited by law shall have "no smoking" signs conspicuously posted so that the signs are clearly visible to all employees, customers, or visitors while in the workplace.

(5) Additional signs may be posted in public areas such as, the following areas: lobbies; hallways; cafeterias; kitchens; locker rooms; customer service areas; offices where the public is invited; conference rooms; lounges; waiting areas; and elevators.

(6) Approved signs and templates for signage design may be obtained from the department of public health or the local boards of health.

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(7) It shall be the responsibility of the establishment to ensure that the appropriate signage is displayed and that an individual or group renting the space enforces the prohibition against smoking.

(h)(a)(1) A smoking bar operating in the commonwealth shall obtain a smoking bar permit from the department of revenue. A permit issued by the department shall be valid for a period of 2 years from the date of issuance unless suspended or revoked. A valid permit that is not suspended at the time of its expiration may be renewed for consecutive 2-year periods.

(2) A non-refundable fee may be required with each permit and renewal application. Each permit issued by the department shall be non-transferable, for a specific location and business; and, only 1 permit may be issued to a business for a specific location during any permit period.

(3) The department shall not issue or renew a smoking bar permit to any business that has not filed all tax returns and paid all taxes due the commonwealth; or is delinquent in filing all declaration statements in connection with the smoking bar permit as required by the department.

(4) The department shall notify the local board of health or municipal health department in the city or town where the establishment is located of any permits issued, renewed, suspended, revoked or reinstated to a business.

(b) A smoking bar shall demonstrate on a quarterly basis that revenue generated from the sale of tobacco products are equal to or greater than 51 per cent of the total combined revenue generated by the sale of tobacco products, food and beverages. The department shall require each business that has been issued a smoking bar permit to submit a quarterly declaration for each 3 month period that the business is in operation; notwithstanding, the first declaration may include a period of not to exceed 4 months. A declaration submitted to the department in connection with a smoking bar permit shall be signed by the owner or business agent under the pains and penalties of perjury. A declaration received by the department shall be confidential and the financial information contained therein shall not be disclosed to the public or any other state governmental agency or department except the attorney general. In the event a business has not filed a required declaration statement, the department shall give written notice to the business that the statement is delinquent and, shall suspend the permit of a business that does not submit the required report after 21 days of the date of notice; but the department shall reinstate the suspended permit within 5 days after receiving the delinquent report.

(c) The department of revenue shall promulgate regulations to implement this section.

(i) Companies which sell ownership rights to owners of time share properties shall distinguish between smoking and non-smoking time share properties. Companies shall disclose to potential buyers whether the unit they are purchasing is a smoking or non-smoking property and post signs accordingly.

(j) Nothing in this section shall permit smoking in an area in which smoking is or may hereafter be prohibited by law including, without limitation: any other law or ordinance or by-law or any fire, health or safety regulation. Nothing in this section shall preempt further limitation of

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smoking by the commonwealth or any department, agency or political subdivision of the commonwealth.

(k) An individual, person, entity or organization subject to the smoking prohibitions of this section shall not discriminate or retaliate in any manner against a person for making a complaint of a violation of this section or furnishing information concerning a violation, to a person, entity or organization or to an enforcement authority. Notwithstanding the foregoing, a person making a complaint or furnishing information during any period of work or time of employment, shall do so only at a time that will not pose an increased threat of harm to the safety of other persons in or about such place or work or to the public.

(l) An owner, manager or other person in control of a building, vehicle or vessel who violates this section, in a manner other than by smoking in a place where smoking is prohibited, shall be punished by a fine of \$100 for the first violation; \$200 for a second violation occurring within 2 years of the date of the first offense; and \$300 for a third or subsequent violation within 2 years of the second violation. Each calendar day on which a violation occurs shall be considered a separate offense. If an owner, manager, or other person in control of a building, vehicle or vessel violates this section repeatedly, demonstrating egregious noncompliance as defined by regulation of the department of public health, the local board of health may revoke or suspend the license to operate and shall send notice of the revocation or suspension to the department of public health. The department of public health shall promulgate regulations to implement this section including, but not limited to notice, collection, and reporting of the fines or license action, and defining uniform standards that warrant license suspension or revocation.

(m)(1) The local board of health, the department of public health, the local inspection department or the equivalent, a municipal government or its agent, and the alcoholic beverages control commission shall enforce this section. In addition, in the city of Boston, the commissioner of health and his authorized agents shall enforce this section.

(2) An individual or person who violates this section by smoking in a place where smoking is prohibited shall be subject to a civil penalty of \$100 for each violation. As an alternative to criminal prosecution, a violation of subsection (1) may also be considered a civil violation. Each enforcing agency under paragraph (1) shall dispose of a civil violation of this section by the non-criminal method of disposition procedures contained in section 21D of chapter 40, without an enabling ordinance or by-law, or by the equivalent of these procedures by a state agency under regulations of the department of public health. The disposition of fines assessed under this section shall be subject to section 188 of chapter 111. Fines assessed by the commonwealth or its agents shall be subject to section 2 of chapter 29. In a city or town having an ordinance of by-law that imposes a fine greater than the fine imposed by this section, the ordinance or by-law shall prevail over this section.

(3) Any person may register a complaint to initiate an investigation and enforcement with the local board of health, the department of public health, or the local inspection department or the equivalent.

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(4) The supreme judicial court or the superior court shall issue appropriate orders to enforce this section and any regulation under it, at the request of any agency mentioned in paragraph (l).

(5) A fine or fee collected by the commonwealth under this section shall be used for the enforcement or for educational programs on the harmful effects of tobacco.

(n) Each local board of health, each local inspection department or its equivalent, and the alcoholic beverages control commission shall report annually to the commissioner of public health, beginning January 1, 2006: the number of citations issued; the workplaces which have been issued citations and the number of citations issued to each workplace; the amount that each workplace has been fined; and the total amount collected in fines. The department of public health shall file a copy of the report with the clerks of the house of representatives and the senate.

(o) The department of public health may issue regulations to implement this section.

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XXIII. LOBBYING

1. LOBBYING

As required by Section 1352, Title 31 of the U.S. Code, and implemented at 28 CFR Part 69, for persons entering into a grant or cooperative agreement over \$100,000 as defined at 28 CFR Part 69, the applicant certifies that:

(a) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the making of any Federal grant, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal grant or cooperative agreement.

(b) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete and submit Standard Form - LLL, "Disclosure of Lobbying Activities," in accordance with its instructions;

(c) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, contracts under grants and cooperative agreements, and subcontracts) and that all sub-recipients shall certify and disclose accordingly.

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XXIV. DEBARMENT AND SUSPENSION

DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS (DIRECT RECIPIENT)

As required by Executive Order 12549, Debarment and Suspension, and implemented at 28 CFR Part 67, for prospective participants in primary covered transactions, as defined at 28 CFR Part 67, Section 67.510.

A. The applicant certifies that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, sentenced to a denial of Federal benefits by a State or Federal court, or voluntarily excluded from covered transactions by any Federal department or agency;

(b) Have not within a three-year period preceding this application been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this application had one or more public transactions (Federal, State, or local) terminated for cause or default; and

B. Where the applicant is unable to certify to any of the statements in this certification, he or she shall attach an explanation to this application.

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XXV. DRUG-FREE WORKPLACE

DRUG-FREE WORKPLACE (GRANTEES OTHER THAN INDIVIDUALS)

As required by the Drug-Free Workplace Act of 1988, and implemented at 28 CFR Part 67, Subpart F, for grantees, as defined at 28 CFR Part 67 Sections 67.615 and 67.620.

A. The applicant certifies that it will or continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an ongoing drug-free awareness program to inform employees about:

(1) The dangers of drug abuse in the workplace;

(2) The grantee's policy of maintaining a drug-free workplace;

(3) Any available drug counseling, rehabilitation, and employee assistance programs; and

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace.

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a), that, as a condition of employment under the grant, the employee will:

(1) Abide by the terms of the statement; and

(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency, in writing, within 10 calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to:

Department of Justice
Office of Justice Programs

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ATTN: Control Desk
810 Seventh Street, N.W.,
Washington, D.C. 20531

Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted:

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e), and (f).

B. The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant: Place of Performance (Street address, city, county, state, zip code). Check ___ if there are workplaces on file that are not identified here. Section 67, 630 of the regulations provides that a grantee that is a State may elect to make one certification in each Federal fiscal year, a copy of which should be included with each application for Department of Justice funding.

States and State agencies may elect to use OJP Form 4061/7. Check ___ if the State has elected to complete OJP Form 4061/7.

DRUG-FREE WORKPLACE (GRANTEES WHO ARE INDIVIDUALS)

As required by the Drug-Free Workplace Act of 1988, and implemented at 28 CFR Part 67, Subpart F, for grantees, as defined at 28 CFR Part 67; Sections 67.615 and 67.620.

A. As a condition of the grant, I certify that I will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant; and B. If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, I will report the conviction, in writing, within 10 calendar days of the conviction, to:

Department of Justice
Office of Justice Programs

Policies and Procedures for Grants and Sponsored Projects

ATTN: Control Desk
810 Seventh Street, N.W.,
Washington, D.C. 20531

As the duly authorized representative of the applicant, I hereby certify that the applicant will comply with the above certifications.

1. Grantee Name and Address:
2. Application Number and/or Project Name:
3. Grantee IRS/Vendor Number
4. Type/Print Name and Title of Authorized Representative
5. Signature
6. Date

OJP FORM 4061/6 (3-91) REPLACES OJP FORMS 4061/2, 4061/3 AND 4061/4 WHICH ARE OBSOLETE.

OFFICE OF JUSTICE PROGRAMS BJA NIJ OJJDP BJS OVC