UNIVERSITY OF ALASKA FAIRBANKS

Biosafety in Research and Teaching

Policy Number: 05-005

Research/Academic Policy

Effective Date: 10/01/2005
Revisions: 6/23/2008

Responsible University Officer

- Vice Chancellor for Research

Responsible University Offices

- Office of Research Integrity
- Institutional Biosafety Committee
- Environmental Health, Safety & Risk Management

Related Policies

- Principal Investigator Eligibility (#05-003)

Policy Statement:

University research and teaching activities, irrespective of purpose or funding source, involving the use of biohazardous materials (see definitions) must be reviewed and approved by the UAF Institutional Biosafety Committee. Activities must be conducted in accordance with all applicable state and federal laws and regulations, as well as, funding agency requirements, university policies and procedures.

The UAF Vice Chancellor for Research is the Institutional Official charged with oversight of all aspects of the university's registration with the Office of Biotechnology Activities, National Institutes of Health. The Director of Environmental Health, Safety & Risk management is responsible for appointing the university's Biosafety Officer and for overseeing disposal of waste biohazardous materials.

Background:

The Institutional Biosafety Committee is charged with oversight of all teaching and research activities involving biohazardous materials as required by Federal Regulation and Board of Regents' Policy. Increased concerns about bioterrorism and national defense with respect to certain organisms and toxins have led to the expansion of the federal Select Agent lists. UAF does not currently hold a Select Agent Registration and cannot hold quantities exceeding the exemption limits of any listed toxin.

Although the University of Alaska Fairbanks acknowledges that the use of biohazardous materials involves certain risks, those risks neither negate nor undermine the value of fundamental and applied research involving biohazardous materials. The university believes that these risks can be mitigated through the use of careful evaluation of projects and procedures, appropriate facilities, engineering controls, personal protective equipment, training, and periodic assessment. This policy sets forth the basic framework for the risk management process as it applies to the use of biohazardous materials in research and teaching at UAF or by university faculty, staff and students.

Definitions:

- **Authorized Personnel** – refers to any person authorized by the Office of Research Integrity to work with biohazardous materials. Such authorization may be given to university faculty, staff, students and volunteers, as well as non-UAF collaborators, visitors and contract service providers, if they fulfill all applicable UAF requirements. Individuals wishing to work with select agents or biohazardous materials that are controlled under U.S. export regulations may have to meet additional requirements (i.e. citizenship criteria, and/or background check) or obtain an export license (see UAF Policy #05-004 *Export Management* for more information).
- **Biohazards or Biohazardous materials** – includes recombinant DNA and infectious agents (bacteria, viruses, protozoa, fungi, etc.) requiring BSL2 or higher protections. Genetically modified organisms are also considered biohazardous materials for the purposes of this policy. Use of genetically modified vertebrates is subject to review and approval by the Institutional Animal Care and Use Committee in addition to the Institutional Biosafety Committee.
- **Biosafety Officer (BSO)** – Appointed by the Director of the UAF Department of Environmental Health, Safety & Risk Management. The primary responsibility of the BSO is to ensure that personnel receive adequate training to safely conduct activities with biohazards. The BSO serves as a resource for principal investigators when writing the safety, security and disposal portions of their IBC Registration(s). This individual serves as a member of the Institutional Biosafety Committee.
- **Institutional Biosafety Committee (IBC)** – the university committee charged with oversight the use of biohazardous materials for research and teaching. Minimum requirements for committee composition are specified in Section IV-B-2-a of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*).
- **Biosafety Registrations** – The form completed by the principal investigator and submitted to the IBC for review. Registrations provide information to the IBC on scientific justification for the research design, personnel qualifications, training, standard operating procedures, health protection and security plans for the acquisition, use, storage and disposal of biohazardous materials.
- **Office of Biotechnology Activities** – this is the office within the National Institutes of Health (NIH) charged with development and implementation of NIH policies and procedures for the safe conduct of recombinant DNA (rDNA) activities and human gene transfer. NIH recipient institutions are required to register with OBA and must abide by the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*).
- **Office of Research Integrity (ORI)** – is the UAF office responsible for ensuring compliance with internal policies and with local, state and federal regulations governing the conduct of research. The ORI provides administrative support for the IBC and institutional official.

Responsibilities:

Obligations of the Administration and University Members

The UAF Chancellor, the Institutional Official, Biosafety Officer, the Office of Research Integrity (ORI), the Institutional Biosafety Committee (IBC) and all units managing or conducting research or teaching activities involving biohazardous materials at the university or at off campus sites are responsible for ensuring that Authorized Personnel shall:

1. follow all applicable laws, regulations, policies, procedures, and guidelines governing the acquisition, transport, storage, use and disposal of biohazardous materials used in research and teaching;
2. be appropriately trained in the regulations, standard operating procedures, security and safety procedures as required by the IBC, prior to engaging in research or teaching activities involving biohazards;
3. respond promptly to requests for information related to biohazards, Biosafety Registrations, and personnel health and safety issues from the Institutional Official, ORI, IBC, or Biosafety Officer;
4. fully participate in the University's Occupational Health & Safety Program;
5. abide by and carry out the decisions of the IBC; and
6. report all concerns, complaints and adverse events regarding the acquisition, use, storage or disposal of biohazards to the Biosafety Officer or ORI.

Principal Investigator

Only individuals meeting the requirements of UAF Policy #05-003 *Principal Investigator Eligibility* may be responsible for university activities involving biohazardous materials.

Principal investigators shall:

1. submit for IBC review and approval a completed Registration application (Registration) for all activities involving biohazardous materials;
2. have their laboratory inspected and approved by the BSO and receive written approval of their Registration from the IBC prior to acquiring or working with biohazardous materials;
3. obtain and maintain all required permits for the work *(Note: The IBC does <u>not</u> require that permits have been received in order to grant approval, but covered activities may not start until the required permits have been issued. Similarly, failure to maintain required permits will result in suspension of biohazard activities until the permit has been reinstated or new permits are issued)*;
4. keep Registrations up-to-date by submitting Modification Requests and Continuing Reviews in a timely manner *(Note: IBC approval is specific to what is in the Registration. Changes or additions to the approved Registration must be reviewed and approved by the IBC prior to implementation.)*; and
5. mentor all project personnel in the safe handling of biohazardous material; at minimum, this means ensuring that all personnel have been informed of any potential health risks and have completed required training before accessing biohazardous material.

Institutional Official

The Institutional Official shall:

1. ensure compliance with all applicable laws, regulations, policies, procedures, and guidelines governing the acquisition, storage, use and disposal of biohazards;
2. appoint the IBC members and designate the committee Chair;
3. implement this policy with the assistance of the ORI, Biosafety Officer and IBC; and
4. ensure prompt filing of all required reports including, but not limited to, self-reporting to regulatory agencies regarding any noncompliance with laws and regulations.

The Institutional Official does not have the authority to approve a program, project or activity that has been denied by the IBC.

Institutional Biosafety Committee

The IBC shall:

1. in consultation with the Institutional Official and Office of Research Integrity establish procedures to implement this policy;
2. ensure that all IBC members are adequately trained in the state and federal regulations, university policies, agency and professional society guidelines and standard operating procedures necessary to reasonably evaluate Biosafety Registrations;
3. review and approve, require modifications in, or withhold approval of Biosafety Registrations;
4. conduct continuing review of previously approved Biosafety Registrations at least annually;
5. evaluate the university's Biosafety program as necessary to ensure compliance with changes in regulations or policy;
6. report any substantiated allegations of noncompliance with federal, state, or university laws, policies, or procedures to the Institutional Official;
7. take any actions, including suspending an activity or revoking approval of a Biosafety Registration, that are in the committee's judgment necessary, to ensure compliance with applicable federal, state, or university polices, procedures, laws and regulations.

Office of Research Integrity

The Office of Research Integrity shall:

1. serve as the primary resource for university members for information about the IBC, Biosafety Registration process, and government regulations related to biohazards;
2. provide administrative support to the Institutional Official and IBC;
3. work with the IBC to develop the administrative procedures necessary to implement this policy;
4. work with the Biosafety Officer to provide appropriate training to individuals working on Biosafety Registrations;
5. conduct post approval monitoring of active Biosafety Registrations;
6. review all allegations of non-compliance and report them as appropriate; and
7. keep the IBC Registration with the NIH Office of Biotechnology Activities current and file all required reports on behalf of the Institutional Official and IBC.

Non-Compliance:

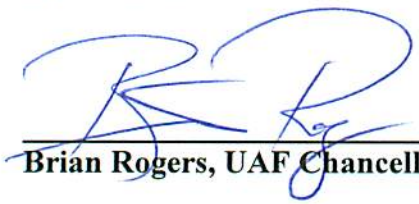
Failure to comply with this policy or associated procedures may be grounds for disciplinary action by the university and, if applicable, suspension or termination of research or other activities, referral for misconduct proceedings, and reporting to state and federal agencies. The Office of Research Integrity will notify the Institutional Official and the supervisor of involved individuals of any non-compliant activities. Any disciplinary action taken by the university will follow the employment rules governing the individual's employment category.

Exclusions:

The collection of specimens purely for diagnostic purposes is not subject to this policy, but shipping of diagnostic specimens is regulated by the U.S. Department of Transportation and, for air transport, by the International Air Transport Association.

Despite the potential for zoonotic disease transmission, the use of legally collected tissues, feathers, fur or hide in museum collections, art projects, or cultural displays is not subject to this policy. Collection activities may require approval of the UAF Institutional Animal Care and Use Committee (see UAF Policy #04-003: *Animal Care and Use*), and State or Federal collection permits.

Approved by:



Brian Rogers, UAF Chancellor

7/1/2008

Date