

# Institutional Biosafety

Academics and Research - Research

**EWU Policy 302-07**

**Effective: December 7, 2018**

**Authority: EWU Board of Trustees**

**Proponent: Vice President for Academic Affairs**

**Purpose:** This policy outlines the standards for research involving the use of recombinant DNA (rDNA), synthetic nucleic acid molecules (SNA) and other potentially biohazardous materials at Eastern Washington University (EWU) and the role of the Institutional Biosafety Committee (IBC) in overseeing research involving potentially biohazardous materials. EWU is committed to protecting faculty, staff, students, research participants, visitors, the general public and the environment from exposures (or potential exposures) to biological hazards. Furthermore, the university is committed to ensuring that all research activity involving biohazardous materials and the facilities used to undertake such activity are in compliance with federal, state and local laws, regulations and guidelines (see Section 1-4 below).

**History:** This policy is new. It was adopted by the EWU Board of Trustees on .

**Applicability:** This policy applies to all EWU employees, students, and persons engaged in research at or sponsored through EWU.

## 1. BIOSAFETY POLICY AND SCOPE

### 1-1. Policy

- a. This policy applies to research that involves potentially biohazardous materials conducted at or sponsored by EWU.
- b. EWU supports the use of recombinant DNA (rDNA), synthetic nucleic acid molecules (SNA) and other potentially biohazardous materials for the advancement of science as long as appropriate safety measures are applied and enforced.
- c. EWU's work with biological materials must, at a minimum, be consistent with the recommendations found in the National Institutes' of Health (NIH) *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and the Center for Disease Control (CDC) publication *Biosafety in Microbiological and Biomedical Laboratories* (BMBL).
- d. EWU will establish and maintain an Institutional Biosafety Committee (IBC) that will be responsible for administering the procedures for compliance with this policy on behalf of the university when research is performed by faculty, staff and/or students. The composition and responsibilities of the IBC are provided below in sections 2-1 and 2-2.
- e. All individuals involved in research at EWU that involves rDNA, SNA and other potentially biohazardous materials must be qualified and adequately trained to perform their duties.

### 1-2. Scope

- a. Inclusions: This policy applies to research involving potentially biohazardous materials conducted at or sponsored by EWU that includes:
  1. rDNA molecules or SNA as defined in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (hereafter *NIH Guidelines*), including transgenic plants and animals.
  2. Biological agents (bacteria, viruses, fungi, protozoa, parasites, and prions) which may cause disease in humans, animals or plants and require containment and safeguards at Biosafety Level-2 (BL2).
  3. Acute biological toxins having an LD<sub>50</sub><100ng/kg or lower in mammals.
  4. Human or nonhuman primate blood, blood products, tissues, secretions, excretions or cell lines including those documented to be free of bloodborne pathogens or otherwise deemed low risk based on a documented risk assessment.
  5. Venomous animals manipulated and/or housed in EWU laboratories or other indoor facilities.
  6. Poisonous plants posing a risk to humans via dermatological contact, inhalation or other route of exposure.
  7. Novel nanoparticles conjugated to biologically active or cell-modifying molecules.
  8. Diagnostic specimens or environmental samples deemed likely to contain any of the above and posing a significant risk to humans, animals, plants or the

environment based on a documented risk assessment.

9. Other potentially biohazardous materials as deemed appropriate by the IBC.

b. Exclusions:

1. No research will be undertaken at an EWU laboratory that includes biohazards contained on the Department of Health and Human Services (HHS) or the US Department of Agriculture (USDA) Select Agents and Toxins List

(<https://www.selectagents.gov/selectagentsandtoxinslist.html>).

2. No research will be undertaken that requires an EWU laboratory at a Biosafety Level-3 (BL3) or Biosafety Level-4 (BL4) containment level.
3. Teaching, diagnostic testing and other activities not considered to be research and involving chemical and/or biohazards are not covered by this policy.

### 1-3. Research

- a. This policy covers basic, applied and clinical research. To conduct research at EWU using potentially biohazardous materials, the research must contribute to generalizable knowledge, have intellectual merit and demonstrate that sound, scientific methods are being used. The research may be supported by external funding and subject to regulation by the National Institutes of Health, the National Science Foundation or another public or private research funder, supported by internal funding provided by EWU or unfunded but conducted under the official auspices of the university.
- b. Research may be undertaken by faculty, staff or students. However, student participation in research involving rDNA, SNA or other potentially biohazardous materials must be under the supervision of a qualified faculty mentor (Principal Investigator [PI]). Undergraduate and graduate students may not be directly responsible for a research project involving a potentially biohazardous material under the terms of this policy.
- c. Visiting faculty and post-doctoral fellows conducting research requiring an IBC review and approval must conduct this work under the oversight of an EWU faculty member who

assumes responsibility for meeting the provisions of this policy.

- d. Research under this policy may be subject to further review and compliance requirements by the Institutional Review Board (IRB) for Human Subjects Research under EWU Policy 302-02 or the Animal Care and Use Committee for Animal Research under EWU Policy 302-03.

### 1-4. Guidelines, Standards, Regulations and Policies

The following guidelines, standards, and policies apply to the possession, use and transfer of biological materials. In the case of a discrepancy between the requirements of the regulatory agencies, the more protective regulations shall prevail, as appropriate.

- a. *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (April, 2016):

[http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.pdf](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.pdf)

- b. The Centers for Disease Control and Prevention/National Institutes of Health (CDC/NIH) Biosafety in Microbiological and Biomedical Laboratories, 5<sup>th</sup> ed. (2009):

<http://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf>.

- c. United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (DURC):

<http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf>

- d. USDA Animal & Plant Health Inspection Services (APHIS) pertaining to biological agents, vectors, pests, and/or recombinant molecules affecting animals (9 CFR, Parts 1-199) and plants (7 CFR, Parts 300-381):
- <http://www.aphis.usda.gov/wps.portal.aphis/home/>

- e. Eastern Washington University Biosafety Manual [in draft as of September 2018].

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## 2. RESPONSIBILITIES

### 2-1. Composition of the Institutional Biosafety Committee

The IBC will be composed of at least five members with collective background knowledge and expertise in rDNA, SNA or biohazardous materials and the capability to assess the safety of research involving biohazards and any potential risks to public health or the environment. Membership shall follow the requirements set forth in the *NIH Guidelines* with regard to member expertise corresponding to research involving plants, animals and/or human gene transfer. Membership shall be reviewed annually.

- a. The EWU IBC shall include at least five permanent members and two external members appointed by the Provost (as delegated by the EWU President), and an undetermined number of standing members.
- b. The IBC will report to the Vice Provost for Academic Administration.
- c. EWU-affiliated permanent members shall include the Dean of College of Science, Technology, Mathematics and Engineering (CSTEM), who will also serve as the Institutional Official (IO), the Executive Director of the Office of Grant and Research Development, the University Safety Officer (SO), and two members of the CSTEM faculty.
- d. The IO will be appointed by the Provost and will serve as the chair of the committee. The IO may appoint a secretary or recorder who is not a member of the IBC to schedule meetings, notify members of meetings, write and distribute meeting minutes which include records of attendance, activities and deliberations of the IBC, typing and distributing IBC documents, receiving and distributing applications to conduct research, recording approval dates for applications, and notifying researchers one month prior to their application renewal dates.
- e. External members must have no direct affiliation with EWU or have a familial or legal relationship with a person who is affiliated with the university. It is preferred that external members have expertise relevant to the work of the committee as well as to the broader mission of protecting public and environmental health.
- f. Additional members may be recommended by the IBC and approved by the IO as needed for their expertise to review applications for research that come before the IBC for review and approval.
- g. Faculty members and external members will have staggered three- and four-year terms. No

member may participate in the review and approval of their own research applications or those in which they hold a financial or other interest (ref. EWU Policy 901-01).

- h. Other experts within and outside the institution may be contacted by the IO or a delegate of the IO if needed in the review of the research if necessary in a non-voting capacity.

## 2-2. Functions of the Institutional Biosafety Committee

The functions of the IBC are to:

- a. Create procedures for review and approval of research using rDNA, SNA, and/or biohazardous materials;
- b. Review and approve, require modifications to, or withhold approval of proposed research using rDNA, SNA, and/or biohazardous materials through a formal application and approval process;
- c. Notify the PI of the results of the IBC's review/approval of the research;
- d. Review and approve, require modifications to, or withhold approval of significant changes to research using rDNA, SNA, and/or biohazardous materials;
- e. Perform independent risk assessment and be responsible for setting the containment level for all experiments as specified in §§ III-D-2a of the *NIH Guidelines*;
- f. Lowering the containment levels for certain experiments as specified in §III D-2 of the *NIH Guidelines*;
- g. Impose sanctions up to and including cancellation of research if the research is not being conducted in accordance with the description that was provided by the PI or PIs and approved by the IBC;
- h. Ensure that significant problems, violations of the *NIH Guidelines* or any significant research-related accidents and illnesses or other adverse events are reported to the NIH Office of Science Policy within 30 days;
- i. Periodically review the research and inspect the work practices and laboratories and research facilities for compliance with the *NIH Guidelines*;

- j. Adopt emergency plans covering accidental spills and personnel contamination resulting from research covered by this policy.
- k. Investigate complaints or concerns and report and make recommendations, as appropriate, to the Vice Provost for Academic Administration (as delegated by the Provost);
- l. Ensure all personnel involved in research approved by the IBC have received adequate training; and
- m. Perform other functions as may be delegated to the IBC by the Vice Provost for Academic Administration.

### 2-3. Biological Safety Officer

The Biological Safety Officer (BSO) is a member of the IBC and is also the primary point of contact with the PIs. The BSO serves as the biosafety program representative for all regulatory and research compliance inspections. The BSO shall:

- a. Manage the EWU biosafety program and ensure that the university has an up-to-date biosafety manual;
- b. Provide technical advice to PIs and the IBC on research safety procedures;
- c. Assist university laboratories in conforming to pertinent laboratory guidelines and IBC policies and procedures by providing facility inspections and communication of biosafety program and related regulatory requirements (dangerous goods shipping, regulated medical waste, etc.);
- d. Develop emergency plans for handling accidental spills/personnel contamination/ investigating laboratory accidents involving biohazardous materials;
- e. Perform periodic inspections of BL2 laboratories for compliance with *NIH Guidelines*, the CDC "Biosafety in Microbiological and Biomedical Laboratories" guide, and the Washington Revised Code 296-823, as applicable;
- f. Provide advice on laboratory security; and,
- g. Prepare periodic reports for the IBC and the Vice Provost for Academic Administration regarding biosafety program status including significant problems or violations of the *NIH Guidelines*.

### 2-4. Vice Provost for Academic Administration

The Vice Provost for Academic Administration is responsible for ensuring that research is conducted

in full conformity with the provisions of the references set forth in this policy. In order to fulfill this responsibility, the Vice Provost shall:

- a. Establish and implement policies and procedures that provide for the safe conduct of research involving biohazardous materials;
- b. Help maintain an active and qualified IBC;
- c. Through the IBC and BSO, ensure compliance with the regulations and guidelines by PIs conducting research at EWU;
- d. Require that all IBC-approved projects include the necessary resources for the operation of safe research;
- e. Work with the IBC and biosafety program to provide adequate resources for the dissemination of information on biohazardous materials and biosafety procedures including training; and,
- f. Represent the IBC as needed to the Provost and President.

### 2-5. Executive Director of Grant and Research Development

The Executive Director of Grant and Research Development is a member of the IBC and is also the research compliance officer on behalf of the university. The Office of Grant and Research Development is responsible for:

- a. Maintaining a secure electronic database with all applications for research involving biohazardous materials;
- b. Archiving all records pertaining to the actions and decisions of the IBC;
- c. Maintaining a file for each application;
- d. Monitoring federal, state and local regulatory trends and communicating any changes to the IBC and BSO;
- e. Communicating biosafety compliance requirements to PIs submitting research grants to external funding agencies;
- f. Ensuring that when research involving biohazardous materials uses human subjects or involves animals, that Institutional Review Board (IRB) and Animal Care and Use (IACUC) policies and procedures followed and approvals are obtained in addition to the compliance requirements under the IBC policy (See also Section 1-3);
- g. Providing records of IBC approval and university compliance to funding agencies;

- h. Ensuring that significant problems, violations of the *NIH Guidelines* or any significant research-related accidents and illnesses or other adverse events are reported to the NIH Office of Science Policy within 30 days;
- i. Providing an up-to-date IBC roster to the NIH;
- j. Generating annual reports to the NIH; and,
- k. Working closely with the Vice Provost for Academic Administration to coordinate all compliance requirements relevant to biosafety.

## 2-6. Department Chairs

Department chairs shall:

- a. Review and approve PI applications to use biohazardous materials;
- b. Ensure that appropriate facilities are available to control biohazardous materials and to enable PIs to comply with environmental health and safety regulations and policies;
- c. Ensure that PIs and any other personnel listed on an application have training that is commensurate with and appropriate for the proposed project;
- d. Ensure that the project design and monitoring methods meet all relevant safety standards; and,
- e. Ensure work practices and laboratory conditions that may result in injury are corrected.

## 2-7. Principal Investigator (PI)

The PI is the person responsible for the scientific or technical direction of any research involving the use of biohazardous materials. The key responsibilities of the PI are to:

- a. Determine whether experiments are covered by § III-E of the *NIH Guidelines* and ensure that the appropriate procedures are followed;
- b. Report any new information bearing on the *NIH Guidelines* to the IBC and to NIH Office of Science Policy, as appropriate;
- c. Comply with all federal and state shipping requirements for the transport of biohazardous materials;
- d. Receive training in the handling of biohazards and ensure that project staff receive training;
- e. Carryout research in accordance with an experimental research protocol that has received prior approval by the IBC;
- f. Develop a risk assessment for physical and biological containment levels in accordance with

- the *NIH Guidelines* when submitting a research application to the IBC;
- g. Develop and implement written laboratory-specific biosafety procedures that are consistent with the nature of current and planned research activities and make available copies of the specific biosafety procedures in each laboratory facility;
- h. Report any significant problems, violations of the policies, practices and procedures to the IBC as soon as reasonably possible; and
- i. Report any emergency situations including accidental spills and personal contamination to the BSO and 911 immediately.

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## 3. TRAINING

- a. All IBC members are required to complete training on laboratory safety and implementation of the *NIH Guidelines* and functions of the IBC on an annual basis. Training must be completed before participation in voting activities of the committee.
- b. Biosafety training, offered through the Collaborative Institutional Training Initiative (CITI) (<http://www.citiprogram.org>), is required for all research personnel.
- c. Research personnel must successfully complete *Training for Investigators, Staff, and Students Handling Biohazards* and *NIH Recombinant DNA (rDNA) Guidelines* training and provide the CITI training certificate as part of the application to conduct research with biohazardous materials.
- d. Training certificates must be kept for a minimum of three years.

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## 4. NONCOMPLIANCE

Violations of this policy may result in one or more of the following university actions:

- a. Suspension of the research until a corrective action plan is approved by the IBC and Vice Provost for Academic Administration and put in place;
- b. When the research is funded by an federal agency, any significant problems or violations of the *NIH Guidelines* must be reported to the NIH Office of Science Policy within 30 days. (Certain types of accidents must be reported on a more expedited basis. Spills or accidents in BL2 laboratories resulting in an overt exposure must

- be immediately reported to NIH Office of Science Policy.);
- c. A report of misconduct to the federal Office of Research Integrity in the case of federally funded research;
  - d. Cancellation of the research; and/or,
  - e. PI, faculty, staff, and/or student discipline, up to and including possible termination or expulsion, dismissal from the university in the case of flagrant noncompliance resulting in a lack of disregard for the protection of other faculty, staff and students and research participants, visitors, the general public and the environment from exposures (or potential exposures) to biological hazards.