



INSTITUTIONAL BIOSAFETY COMMITTEE BYLAWS & OPERATING PROCEDURES

Revised and approved 1/7/2020

I. Introduction

The Institutional Biosafety Committee (IBC) is established by the authority of the President of the University of Oregon (UO). The Committee is delegated primary responsibility for the safe use of recombinant or synthetic nucleic acid molecules as required by Section IV-B-1 of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (hereafter referred to as the *NIH Guidelines*). Compliance shall be reviewed for all aspects of the University operation including, but not limited to, instructional, research, and support functions for research the University sponsors or participates in. Through this authority, the Committee serves as the administrative body to review and approve all uses of these materials. The bylaws shall be amended as needed by vote of the committee.

II. IBC Responsibilities

The UO IBC is responsible for reviewing proposed research for compliance with the *NIH Guidelines* including the following:

- Determination of the appropriate containment level for the work being proposed
- Assessment of the laboratory facility, practices and procedures, and training as presented for the research registration
- Assessment of the emergency plan covering spills and personnel exposures resulting from such activities

The Committee will respond to requests from other institutional entities (e.g., University Health Center, Animal Welfare Services) or individuals for consultation on related biosafety activities.

The UO IBC has responsibility for research the University sponsors or participates in throughout the entire University enterprise. IBC members are appointed by the UO Vice President for Research. The EHS Laboratory Safety Office staff will support the IBC in carrying out its charge. The IBC is authorized to inspect research facilities, approve research practices and procedures, and to take actions, including cessation of laboratory or research activities, in the event of an unsafe workplace situation.

General Policy for IBC Oversight

All work involving recombinant or synthetic nucleic acid molecules (rsNA) must be registered with the IBC. Experiments categorized in Sections III-A, III-

B, or III-C must be approved by the IBC *as well as* approved by the NIH Recombinant DNA Advisory Committee (RAC) and/or NIH Office of Science Policy prior to initiating work.

The following types of experiments must be reviewed and approved by the IBC prior to initiation of work:

- Experiments categorized in Sections III-D and III-E
- Pathogens designated Risk Groups 2 and higher
- Materials derived from non-human primates (e.g., tissue, cell culture, samples)
- Biological Select Agents and Toxins, as listed in the [Select Agents and Toxins List](#) (PI must be registered with the CDC and/or USDA, as well as receive approval from the IBC)
- Dual Use Research of Concern - The IBC will review research identified as having dual use potential by the PI and verify the finding. With input from the PI, the IBC will conduct a risk-benefit analysis, and develop a risk mitigation plan. The IBC will notify the PI, and NIH when required, of the results of the review process.

The following experiments are exempt from the *NIH Guidelines*, but still require registration with the IBC:

- Experiments categorized in Section III-F
- Possession or use of Select Agent Toxins in quantities below the permissible toxin amounts
- Non-recombinant work involving human cell culture or manipulation of human-derived materials

III. IBC Membership

- A. The Committee shall consist of no less than five members. The membership shall include, but is not limited to:
1. The UO Biosafety Officer (BSO)
 2. Two members who are not affiliated with the UO
 3. At least one representative with expertise in animal containment principles
 4. One individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P require prior approval by the IBC.
- B. All members are appointed by the Vice President for Research and Innovation for a three-year term, which is renewable. The IBC Chair is appointed by the Vice-President for Research and Innovation.
- C. In addition to the abovementioned members, the Committee shall include *ad hoc* members who represent the diversity of scientific disciplines using

rsNA, Select Agents and Toxins, or other relevant research conducted at the University.

- D. Regular voting members may recommend an alternate voting member to substitute for them at regularly scheduled meetings. The alternate must be appointed in the same manner as the regular committee member and must have the same area of expertise.

IV. IBC Management

The UO BSO will be responsible for keeping records, recording minutes, and scheduling meetings for the IBC. This will include preliminary review of submitted registration forms for completeness of information required for IBC review. No project requiring IBC approval will commence prior to IBC approval of the registration.

The IBC will meet at least quarterly and more frequently when necessary to expedite the approval process. The IBC will follow these procedures:

- A. All registrations are due in complete form to the EHS office in advance of the IBC meeting. The BSO shall assign a tracking number to each registration for tracking purposes. A separate registration will not be needed for each grant proposal unless a different host/vector/insert system will be used.
- B. The BSO will work with the researcher to modify the form as necessary prior to committee review. The Principal Investigator (PI) receiving grant funds to conduct the research must be listed as the PI on the registration form.
- C. The BSO will finalize the registrations and agenda no less than three days prior to the IBC meeting, and will distribute meeting materials, requesting review prior to the meeting. The chair and/or BSO will assure appropriate expertise is available for review of the registrations.
- D. The IBC approves registrations by a majority vote of the attendance at a designated meeting. Although information regarding registrations may be communicated by email, voting must occur at a designated meeting. Meetings must be held in person or via conference call.
- E. Registrations that require IBC notification rather than IBC approval will be administratively approved by the BSO and reported at the meeting.

A quorum for the meeting is defined as no less than 50% of voting members present. It is preferred that a community member be among those present at every meeting.

Registration approvals are valid for three years. If changes are to be made to a registration, the PI shall submit a revised registration form delineating the updated aspects of the work. Significant changes may require submission of a new registration form. Changes in personnel may be approved administratively.

Conflict of Interest Policy

As required by the *NIH Guidelines*, Section IV-B-2-a-(4), no member of an IBC may be involved in the approval of a project in which he/she has been or expects to be engaged or has a direct financial interest, except to provide information requested by the IBC. No member of the UO IBC will vote on a registration with which he or she has any connection or in which he or she has a personal or professional interest other than as a member of the IBC.

Confidentiality

It is expected that IBC members will not disclose the details of meetings or associated submissions with individuals not affiliated with the IBC. Such disclosures could compromise Principal Investigators' research goals and proprietary interests as well as the willingness of members to conduct open discussions. Members contacted for information should forward requests to the BSO, who will consult with the UO Legal Counsel and the Public Records Office as appropriate.

V. IBC Minutes

The BSO will develop meeting minutes to be approved at the subsequent meeting of the IBC. The minutes will include the date of the IBC meeting; the location; meeting attendees; rsNA or IBC business; and reviewed registrations including, at a minimum, for each:

- The IBC tracking number
- Title of the registration
- A brief description of the proposed work
- The approved biosafety level of containment
- Any additional requirements for approval
- The applicable section(s) of the *NIH Guidelines*
- The final voting outcome of the registration

Identifiers that are potentially sensitive, such as names and lab locations, will not be included in the minutes.

Members of the public requesting copies of the IBC minutes will be directed to the UO Office of Public Records, <http://publicrecords.uoregon.edu>. UO makes available meeting minutes upon request. However, UO reserves the right to redact any confidential, private, or proprietary information, including faculty records and trade secrets.

VI. IBC Reporting

At least annually, the IBC shall submit to the NIH a current roster of IBC members, noting the chair, along with biographical sketches of all IBC members (unless not significantly modified from the previous year).

Any problems associated with IBC-registered work, including violations of *NIH Guidelines*, accidents, exposures or illnesses associated with a research registration must be reported to the IBC and the Cass Moseley, UO Institutional Official. Amendment of the registration, re-review of the registration by the IBC, and/or reporting to the NIH OSP may be required.

Any significant problems with rsNA research, significant violations of the *NIH Guidelines*, or significant research-related accidents, exposures and illnesses will be reported to NIH within 30 days of the notification of the IBC and IO. The following are examples of reportable incidents:

- Skin puncture with a needle containing recombinant or synthetic NA
- The escape or improper disposition of a transgenic organism
- A spill of high-risk rsNA materials occurring outside of a biosafety cabinet (BSC)

The NIH OSP will be consulted if there is uncertainty as to whether reporting is warranted.

The IBC will provide the NIH with any public comments on IBC actions, along with the IBC's response to the comments, within 30 days of such public comment.

VII. Other Stakeholder Responsibilities

Environmental Health and Safety (EHS), Biological Safety:

- Keeps a database of UO IBC registered and approved research registrations
- Receives registration forms and prepares them for IBC review and/or approval
- Ensures that all laboratories submitting IBC registrations for approval have been audited for compliance with the proper safety levels, and conducts annual laboratory audits to ensure compliance with the *NIH Guidelines*
- Keeps records of IBC registrations, any correspondence with PIs and the IBC members, and minutes of IBC meetings.
- Annually reviews research registrations with the PI and incorporates any updates
- Communicates decisions of the IBC with the PIs

Principal Investigators:

- Makes an initial determination of the required levels of physical and biological containment, and practices and procedures in accordance with the *NIH Guidelines*; determines applicable section(s) of the *NIH Guidelines*

- Submits the appropriate paperwork for the proposed work; initiates modifications, amendments, resubmissions, or notifications of discontinued work
- Is responsible for adherence to all requirements of the *NIH Guidelines*, including required safety practices
- Ensures all laboratory workers are trained regarding the potential hazards of the work and precautions to be taken, and/or facilitates training with EHS
- Reports any significant problems or illnesses pertaining to the operation and implementation of containment, or any adverse reactions occurring during clinical studies to EHS for review by the IBC
- Ensures that all lab workers experiencing occupational exposures to rsNA material will report such exposures to EHS and the IBC. This report should be in writing and include: who was involved, how the event occurred, what was the rsNA material, what was done to mitigate, treat, or clean up the rsNA
- Complies with applicable shipping and permitting requirements
- Ensures that laboratory workers who work with animals involved in the work participate in the UO Occupational Health Program for Animal Handlers
- Ensures medical surveillance recommendations or requirements are described in each lab's Standard Operating Procedures (SOPs), if needed

Employee Occupational Health Program:

- Ensures a risk assessment is performed based on specific hazards associated with the research, including input from the BSO, PI, and healthcare professionals specializing in infectious diseases or occupational health, as appropriate
- Determines appropriate occupational health requirements (e.g., vaccinations) and recommendations, and ensures that these are communicated to the PI and laboratory workers.
- Provides hazard awareness and exposure prevention training as necessary
- Coordinates medical services associated with rsNA work (evaluation, prophylaxis, and incident response) for laboratory workers
- Maintains procedures for voluntary reporting of immunocompromising conditions
- Reports occupational exposures to rsNA material to the BSO, and subsequently, to the NIH OSP if applicable