



Institutional Biosafety Committee Charter

Approved 7-7-14

Purpose

Western Washington University has established an Institutional Biosafety Committee (IBC) whose responsibilities are described in the National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*. Because the *NIH Guidelines* are applicable to all recombinant DNA research that is conducted at or sponsored by any institution that receives support from the National Institutes for Health, they are applicable to everyone who participates in research, instruction, or work at Western. Committee areas of responsibility include:

- Review of recombinant DNA activities regulated under the *NIH Guidelines*;
- May review recombinant DNA activities exempt from the *NIH Guidelines*; and
- May review other biological safety considerations or recommend review by qualified experts.

The University is ultimately responsible for the effectiveness of the IBC and may establish or modify committee policies and procedures, as long as compliance with the *NIH Guidelines* is maintained.

Reporting

This committee is appointed by and reports to the Provost through the Vice Provost for Research, but may provide recommendations or concerns directly to individual researchers, department heads, deans, or other vice presidents.

The IBC corresponds directly with the National Institutes of Health/Office of Biotechnology Activities ([NIH/OBA](#)) as appropriate via the Environmental Health and Safety Office.

Membership

The IBC shall be comprised as specified in Section IV-B-2 of the *NIH Guidelines*. It shall have a minimum of five members as specified in the *NIH Guidelines*. These members are selected so that they collectively have the following characteristics:

- Experience and expertise in recombinant DNA technology,
- The capability to assess the safety of recombinant DNA research, and
- The capability to identify any potential risk to public health or the environment.

Committee make-up shall include:

- In accordance with Section IV-B-2, two of the five members shall not be affiliated with the University (apart from their membership on the IBC). They are to represent the interest of the surrounding community with respect to health and protection of the environment. Persons from state or local public health or environmental protection agencies, members of local governments or persons active in medical, occupational health or environmental concerns in the community are potential candidates for membership.
- The IBC shall include at least one scientist with expertise in plant containment principles when experiments utilizing [Appendix P](#), *Physical and Biological Containment for Recombinant DNA Research Involving Plants*, require IBC approval.
- The IBC shall include at least one scientist with expertise in animal containment principles when experiments utilizing [Appendix Q](#), *Physical and Biological Containment for Recombinant DNA Research Involving Animals*, require IBC approval.
- The Director of Environmental Health and Safety is a member of the committee.
- At least one member of the IBC shall be a person with expertise in recombinant DNA technology, biological safety and physical containment.
- One member represents laboratory technical staff.

- One member represents the Vice Provost for Research.
- The IBC will include or have available as consultants persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes and the environment.
- Committee members may not be involved with a review of any research with which they are financially or otherwise affiliated.

Term of Membership

Committee appointments will be for three years and members may be re-appointed.

Biological Safety Officer

The Environmental Health and Safety Director, if required because of large-scale research or production activities, will function as Western's Biological Safety Officer

Meetings and Minutes

Meetings are held when necessary for committee business. Meetings held may be open to the public, when consistent with protection of privacy and proprietary interests. Meeting minutes are available for public review.

Meeting minutes may be redacted as appropriate, before being made public. Redaction will be based on a legal review by an assistant attorney general.

If urgently required, approvals associated with recombinant DNA activities may be obtained when a majority of members approve in writing without a meeting.

Committee Functions

The following are functions of the IBC:

1. Review non-exempt recombinant DNA research or teaching conducted at or sponsored by Western for compliance with the *NIH Guidelines*. Approve those projects that conform to the guidelines. This review includes:
 - Independent assessment of the containment levels as required by the *NIH Guidelines*; and
 - **Assessment of the facilities, procedures, practices, training and expertise of the personnel involved with the recombinant DNA research.**

A member of the IBC may not be involved in review or approval of a project in which he/she expects to be engaged or has a direct financial interest, except to provide requested information.

2. May review exempt recombinant DNA research and teaching for the above assessment parameters.
3. Notify the principal investigator/faculty member of the results of the IBC review and approval or disapproval.
4. Lower containment levels for certain experiments as specified in the *NIH Guidelines*.
5. Set containment levels for experiments involving whole animals or whole plants as delineated in the *NIH Guidelines*.
6. Periodically review previously approved recombinant DNA research conducted at the University to ensure on-going compliance with *NIH Guidelines*.
7. Delegate to subcommittees or individual committee members various aspects of assessment, such as but not limited to, training documentation review and laboratory inspections.
8. Ensure that laboratory inspections of recombinant DNA research facilities regulated under the *NIH Guidelines* are performed periodically and corrective action is taken.

9. Adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research.
10. Report any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the Provost and the NIH/OBA within 30 days unless the IBC determines that a report has already been filed.
11. May review other biological safety issues as may occur at the University or recommend review by qualified experts.
12. Perform such other biological safety-related functions as may be delegated by the Provost or Vice Provost for Research.

Environmental Health and Safety Office Responsibilities

The Environmental Health and Safety Office reports annually on membership in the IBC to the National Institutes of Health as specified in the *NIH Guidelines*. The office provides all reporting, minutes, correspondence with principal investigators/faculty and campus administrators, and other documentation supporting the IBC.

Upon request, the Environmental Health and Safety Office shall make available to the public all IBC committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public. If public comments are made on IBC actions, the office shall forward both the public comments and the IBC response to the NIH's Office of Recombinant DNA Activities.

The Environmental Health and Safety Director has the authority to immediately close any laboratory in which a required safety procedure is violated, if that procedure endangers personnel or property.

The Environmental Health and Safety Director functions as chair of the committee and, if required because of large-scale research or production activities, functions as Western's Biological Safety Officer.

Recombinant DNA Procedures

Each Principal Investigator (faculty member) responsible for research or teaching activities involving the use of recombinant DNA molecules or related activities files a registration form developed by the Environmental Health and Safety Office, provides appropriate information and a resume or curriculum vita for the committee.

Completed registration forms are reviewed by the EHS office. If research or teaching is regulated under the *NIH Guidelines*, an IBC meeting is convened for the purpose of reviewing the research information and the research project is approved or denied as described above. The Environmental Health and Safety Office communicates committee decisions and maintains appropriate records, including archiving of all records.

Each person working with a faculty member on a research or teaching project involving recombinant DNA using organisms or procedures which are not exempt from the *NIH Guidelines* must complete a statement of training and experience documenting his/her education and work history. This form also documents the training provided by a faculty member in relevant safety and protective practices.

If teaching involves activities that are not exempt from the *NIH Guidelines*, all teaching assistants and technicians are to complete the required statement of training and experience.

Each statement of training and experience is reviewed in accordance with IBC guidelines and may be reviewed by a sub-unit of the committee. The Environmental Health and Safety Office personnel communicate decisions.

Committee Administrative Procedures

The IBC may adjust administrative procedures relating to Recombinant DNA research and teaching by majority vote.

New policies or procedures significantly impacting faculty research or teaching related to Recombinant DNA are recommended by the IBC and, when approved by the Provost, are carried out by individuals and offices as designated by the Provost.

All regular members of the IBC have voting rights. If an ex officio member were appointed for any reason, that person would not have voting rights. Committee members must abstain from voting on their own protocols or any work in which they have a scientific or financial part.

The IBC may take action or recommend action in instances where personnel or property may be endangered.

A principal investigator may appeal an IBC decision to the Vice Provost for Research and, then, the Provost. The appeals may alter a committee decision if the change is in accordance with *NIH Guidelines* and does not conflict with the committee's ability to set biosafety and physical containment levels.

A quorum consists of 50 percent or more of the voting members.

Approval of motions requires a majority of members present.

Approvals of recombinant DNA activities may be accomplished by a majority of members in writing without conducting a formal meeting, if specific circumstances preclude convening a meeting. This is only done if urgently required due to the undesirable absence of public notice.

Amendments to the Charter

Charter amendments may be made by the Environmental Health and Safety Director to keep the committee in compliance with changes to the *NIH Guidelines*.

IBC members may recommend an amendment to the charter if the amendment is approved by 75 percent of voting IBC members. The recommended amendment must be presented to the Vice Provost for Research and the Provost. Recommended amendments become effective upon approval of the administration. All charter amendments must maintain Western's compliance with *NIH Guidelines*.