Institutional Biosafety Committee
Program Guide

Division of Research and Economic Development
Office of Research Compliance

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1. INTRODUCTION

The Institutional Biosafety Committee Guide is a reference document detailing guidance and processes of the University’s Institutional Biosafety Committee (IBC) and review requirements for research and academic activities involving biohazardous materials.

These processes are guided by regulatory obligations, federal guidance, and University policies and written programs, such as:

- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)
- Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- Select agent regulations, Centers for Disease Control and Prevention (CDC) and United States Department of Agriculture (USDA)
- Bloodborne Pathogens – Occupational Safety and Health Administration (OSHA) and Idaho Division of Building Safety (DBS)
- University Policy 5080 - Biosafety
- University Biosafety Manual
- University Bloodborne Pathogen Exposure Plan

It is important to note this guide is subject to change due the ever evolving activities involving biohazardous materials conducted by members of the University and their regulation.

2. IBC PURPOSE, SCOPE, AND AUTHORITY

The IBC is charged with reviewing research and academic activities, regardless of funding, involving biohazardous material to protect the University, employees, students, visitors, surrounding community and the environment as well as assist the University and Principal Investigators (PIs) in adhering to regulatory requirements and guidelines.

The Vice President for Research and Economic Development (VPRED) has delegated certain responsibilities to the IBC to ensure compliance with the University’s regulatory obligations in regard to biohazardous materials. IBC authority and scope is outlined in University Policy 5080.

The IBC has the authority to:

1. Approve, not approve, or require modification of activities involving biohazardous material to ensure compliance with regulatory obligations and University policies and programs;
2. Suspend or terminate activity approval based upon non-compliance with regulatory obligations or University policies and programs;
3. Report approval status in accordance with agency requirements; and
4. Report non-compliance to the Vice President for Research (through the Office of Research Compliance) and appropriate agencies as required.
3. ROLES AND RESPONSIBILITIES

3.1. Federal

Multiple federal agencies provide regulatory requirements and guidance regarding biohazardous materials. They are responsible for varying levels of oversight including enforcement and penalties for noncompliance. For example, the NIH has the ability to relinquish funding for any or all NIH sponsored activities if the University is not in compliance with the NIH Guidelines. The NIH also provides review and approval for certain categories of activities as outlined in the NIH Guidelines.

3.2. University

The University is committed to fulfilling the requirements and guidance set forth by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and other applicable agencies regarding the safe handling of biohazardous materials.

The University conducts research involving recombinant DNA, and in doing so, must utilize an IBC to review and approve activities involving recombinant DNA in accordance with the NIH Guidelines. The University also requires activities involving other biohazardous materials to be reviewed and approved by the IBC.

3.3. Vice President for Research and Economic Development (VPR)

The Vice President for Research and Economic Development shall:
1. Ensure compliance with all applicable laws and policies related to the IBC;
2. Appoint an IBC with appropriate administrative support;
3. Have proper administrative and operational authority to develop administrative procedures necessary to comply with applicable regulatory requirements, University policies and associated programs;
4. Review the composition of the IBC membership to ensure efficiency and a balance of interests with consultation from the IBC Chair and the Director of the Office of Research Compliance (ORC);
5. Perform all necessary reporting requirements; and
6. Report to appropriate officials any noncompliance with laws and policies, as well as any corrective or remedial action taken.

The VPR delegates certain responsibilities to the Office of Research Compliance and IBC.

3.4. Office of Research Compliance

The Office of Research Compliance (ORC) provides administrative support and oversight of the IBC and helps guide Principal Investigators through IBC processes. ORC is responsible for:
1. Coordinating the protocol review process and IBC meetings;
2. Serving as a liaison between the IBC and Principal Investigators;
3. Recording meeting minutes;
4. Serving as the official record keeper for IBC documents;
5. Developing IBC processes and guidance; and
6. Providing biosafety training for IBC Members, Principal Investigators, and Key Personnel.

3.5. Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) has responsibility to:
1. Review research and academic activities involving biohazardous materials and determine appropriate level of review based upon the material, activity, and associated risk;
2. Approve, not approve, or require modification of activities involving biohazardous material to ensure compliance with regulatory obligations and University policies and programs;
3. Suspend or terminate activity approval based upon non-compliance with regulatory obligations or University policies and programs;
4. Report approval status in accordance with agency requirements; and
5. Report non-compliance to the Vice President for Research (through the Office of Research Compliance) and appropriate agencies as required.

3.6. Principal Investigators

A Principal Investigator (PI) is the person directing the research project or academic activity. A PI conducting activities involving biohazardous materials, regardless of funding source, must adhere to federal regulations and guidelines, University policies, and this program guide. Situations may arise where activities may be covered by another institution’s IBC; however, cases where the activity is directed or co-directed by a member of the University community require review and approval by the University’s IBC.

Principal Investigators (PI) are responsible for:
1. Informing the IBC of their work with biohazardous materials
2. Ensuring personnel conducting activities covered by an IBC protocol are listed as Key Personnel
3. Ensuring Key Personnel complete applicable training including laboratory specific topics.
4. Not beginning covered activities until reviewed and approved by the IBC.

PI Eligibility

The IBC follows the eligibility requirements under University Policy 5020 – Principal Investigator Eligibility. An individual requiring a PI exception for a project with no external funding must contact the IBC Coordinator for instructions and the ORC PI Exception Form. An individual external to the University may be a PI; however a review fee applies. See External Review for more details.
3.7. Key Personnel

Key personnel are individuals carrying out research activities with biohazardous materials or an individual overseeing activities with biohazardous materials in an academic setting. A PI is considered Key Personnel. Key personnel are responsible for:

1. Conducting activities in a safe manner and following lab procedures/protocols.
2. Reporting incidents to their supervisor/PI and/or the IBC.
3. Reviewing and understanding the IBC protocol and its scope and safety requirements.
4. Completing applicable safety and lab specific training.

4. MEMBERSHIP AND COMPOSITION

4.1. Membership Types and Roles

Chair
The IBC Chair is a Member appointed by the VPRED. The Chair works closely with the IBC Members, ORC, and PIs to ensure activities with biohazardous materials are conducted safely. The Chair is responsible for activities of the committee such as conducting monthly meetings, calling for additional meetings as necessary, assigning reviewers for Designated Member Review, reviewing policies and programs, and signing official IBC documentation as needed.

Plant Expert
At least one Member must have expertise in plant, plant pathogen, or plant pest containment when reviewed activities fall under Appendix P of the NIH Guidelines.

Animal Containment Expert
At least one Member must have expertise in animal containment when reviewed activities fall under Appendix Q of the NIH Guidelines.

Human Participant Expertise
The committee must have relevant expertise with recombinant DNA activities involving human research participants if the IBC will review these type of activities. This may be fulfilled by Member expertise and training or the use of ad hoc consultants.

Biological Safety Officer
A Biological Safety Officer (BSO) is mandatory and must be a Member of the IBC if the University conducts any recombinant DNA activities under Biosafety Level (BSL) 3, BSL4, or large scale conditions (involving more than 10L).

Community Member
Individuals serving in this capacity represent the community with respect to health and protection of the environment and have no obvious affiliations with the University aside from serving on the IBC.
Ad Hoc Consultant
An ad hoc consultant may be used to provide expertise when that expertise is not available from one of the Members. An ad hoc consultant is not a voting Member of the committee.

4.2. Number of Members
The NIH Guidelines require the committee consist of no fewer than five Members with relevant expertise for the activities being reviewed. A minimum of two of these Members must be Community Members. The VPRED ensures appointed Members are sufficiently qualified through experience and training and meet the membership requirements outlined in the NIH Guidelines.

4.3. Membership Terms
The VPRED appoints Members to the IBC, and Members typically commit to serving for a minimum of three years. The VPRED, in consultation with the IBC Chair and ORC, annually review memberships to ensure appropriate committee representation and composition and commitment of its Members. Members serve at the discretion of the VPRED and may be removed or replaced.

4.4. Member Education

CITI
All IBC Members must complete all of the CITI biosafety training modules and refresher courses as required.

Additional Training
Continuing education materials are offered to IBC Members on a regular basis to keep them apprised developments in biosafety. These materials may be in the form of webinars, meeting discussions, or publications. Reference materials, such as this guide the NIH Guidelines, and the BMBL, are provided electronically.

4.5. Liability Coverage
The University offers protection for its employees and authorized volunteers who are sued for duties and actions performed in the course of their employment and in good faith under the University’s liability and workers compensation insurance.

IBC Members who are not employees of BSU are considered authorized volunteers and are required to fill out an Authorized Volunteer Services Agreement Form. The signed forms will be kept on file within the Office of Research Compliance. In the event of a claim, the Office of Risk Management and Insurance will request the signed Authorized Volunteer Services Agreement Form from the Office of Research Compliance.
5. IBC PROCESSES

The IBC is responsible for assessing the risk of activities involving biohazardous materials. This assessment is mainly done through the use of various forms submitted by a PI which summarize the biohazardous materials they wish to use, what they plan to do with them, controls in place to minimize risk, where they would like to conduct the activities, and who will perform the activities.

5.1. Review Mechanisms

The level of review is based upon the type of submission and potential risks associated with the activities involving biohazardous materials as well as requirements under the NIH Guidelines. Aside from Administrative review, the Chair determines the initial level of review.

Designated Member Review (DMR)
DMR is a review mechanism where the Chair selects suitable Members (typically 1-3) to review the protocol. DMR may be utilized for activities with lower risk or when not required by the NIH Guidelines. DMR is typically quicker than Full Committee Review since it is conducted outside a convened meeting. After the Chair calls for review by DMR, the entire committee is sent the protocol documents. Each Member not assigned as a reviewer is given a three day window to review the materials and call for a Full Committee Review if they wish. Otherwise the decision is left to the assigned reviewers. Assigned reviewers must reach consensus to approve the protocol. Any questions/concerns are relayed to the PI and responses returned to the assigned reviewers. If consensus to approve cannot be reached, the protocol will move to full committee review.

Full Committee Review (FCR)
FCR is utilized to review activities with increased risk or if required by the NIH Guidelines. See Committee Meetings for additional information regarding FCR processes.

Administrative Review
ORC may review renewals and modifications of approved protocols for changes to:

- Key personnel
- Funding source
- Contact information

Pre-Review
The IBC Coordinator strives to conduct a pre-review of each submission before it moves along the review process. Pre-review frequently speeds up the review process by addressing typical concerns the committee Member’s raise. The IBC Chair may also perform pre-review
5.2. Types of Submissions

New protocol application
The IBC protocol application is the primary tool of the review process. The PI uses it to communicate to the IBC what they are doing, the risks involved, controls in place, and who will perform the activities.

Modification
The PI must seek approval for any changes or additions to previously approved activities. This includes changes in personnel, funding sources, locations, biohazardous materials, or activities with those materials.

Renewal
The IBC typically approves new protocols for a period of one year. A protocol may be renewed on an annual basis up to two times to keep the protocol open unless the IBC stipulates more stringent requirements.

Final Report
The PI must submit a final report to close the protocol if the protocol is within its approval period and the activities will not continue.

Incident Report
Incidents involving biohazardous materials covered under an approved application or required by the NIH Guidelines must be reported to the IBC in a timely manner. Incidents include exposures to biohazardous materials as well as spills. The IBC utilizes the University’s reporting mechanisms through Environmental Health, Safety and Sustainability and the Office of Risk Management and Insurance. Incidents should be reported through ReportExec. Injuries must be reported through the Supervisor’s Accident Report.

5.3. Path of Review
A biosafety protocol must be reviewed through a Full Committee Review (FCR), Designated Member Review (DMR) or Administrative Review. The Chair determines the initial review of a protocol unless it falls under Administrative Review. Below are the typical paths of review based upon the risk and submission type:
<table>
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<tr>
<th>FCR</th>
<th>New Protocol</th>
<th>Renewal or Modification</th>
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<tr>
<td></td>
<td>• Risk Group 2* or above</td>
<td>• Increase in risk group *</td>
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<tr>
<td></td>
<td>• Biosafety Level 2* or above</td>
<td>• Increase in biosafety level*</td>
</tr>
<tr>
<td></td>
<td>• Biological toxins</td>
<td>• Significant change in procedures</td>
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<td></td>
<td>• Select agents</td>
<td>• Significant change in species, organisms, etc.</td>
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<tr>
<td></td>
<td>• NIH Guidelines require IBC approval</td>
<td>• Change in PI</td>
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<tr>
<td></td>
<td>• Any IBC Member requests FCR for protocol</td>
<td>• Any IBC Member requests FCR</td>
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<tr>
<th>DRM</th>
<th>New Protocol</th>
<th>Renewal or Modification</th>
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<tbody>
<tr>
<td></td>
<td>• Risk Group 1</td>
<td>• Minor change in procedures</td>
</tr>
<tr>
<td></td>
<td>• Biosafety Level 1</td>
<td>• Minor change in species, organisms, etc.</td>
</tr>
<tr>
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<td>• Change in location</td>
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<th>Admin</th>
<th>New Protocol</th>
<th>Renewal or Modification</th>
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<tr>
<td></td>
<td></td>
<td>• Key personnel updates</td>
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<td>• Funding source updates</td>
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<td>• Contact information</td>
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The IBC Protocol Review Work Flow outlines the review path along with the criteria for each path.

### 5.4. Approval Periods

Each approved protocol typically has a three-year life cycle and is allotted two annual renewals. If the activities are not complete by the third year, the PI is required to submit a new protocol application for review and approval instead of another annual renewal form. The IBC may approve protocols with shorter approval periods and may stipulate the protocol cannot be renewed meaning a new protocol application must be submitted for review. Modification approval does not change the protocol’s approval period.

### 5.5. Committee Meetings

The IBC convenes meetings on a [monthly basis](#) to review submissions requiring full committee review (FCR) and other committee business. Additional meetings may be convened if the need arises.

**Quorum Requirements**

A quorum of more than half of the voting membership is required to conduct business. Members may attend the IBC meeting by video conference or by telephone. IBC Members who may have a potential conflict of interest with the activities under review must be recused from the vote and will not be counted as part of the quorum. See [Conflict of Interest](#) for additional information.
Motions
After a submission is discussed and reviewed, a Member must call for a motion. A motion should be one of the following:

1. Approve;
2. Conditionally approve with modifications to be confirmed by DMR;
3. Conditionally approve with modifications to be confirmed by ORC;
4. Send the submission be sent back to the PI for modification with the modifications to be reviewed and approved by FCR;
5. Table; or
6. Not approve.

Voting
Each Member has one vote and no proxy votes are allowed. Members must vote for, vote against, or abstain from voting on a motion. A Member choosing to vote against or abstain from the vote may request their reason be noted in the minutes.

Submission Due Dates
Submissions requiring FCR must be received a minimum of two weeks prior to a scheduled meeting. This time period is necessary for pre-review and allow Members sufficient time to review the submission prior to the meeting. Due dates are available on the ORC IBC webpage.

PI Attendance
A PI is often invited and strongly encouraged to attend meetings to summarize their planned activities and to answer any questions or concerns from the committee. The IBC Coordinator will send a meeting invitation to the PI roughly one week prior to the scheduled meeting.

Meeting Minutes
Meeting minutes provide a summary of the committee’s business and deliberations. They are drafted by the IBC Coordinator and the previous meeting’s minutes are reviewed at the subsequent meeting.

5.6. Approval Suspension and Termination
The IBC has the authority to suspend or terminate activity approval based upon non-compliance with regulatory obligations or University policies and programs. Typically, the IBC Chair and/or IBC Coordinator will work with the PI to resolve any issues. The IBC must vote on a suspension or termination of approval at a convened meeting.

6. FACILITY AND PROGRAM INSPECTIONS
The IBC may conduct facility and/or program inspections to ensure activities with biohazardous materials are being conducted safely and in suitable facilities. Inspections may be done
independently or as a part of an Environmental Health, Safety and Sustainability laboratory safety assessment.

7. IBC ADMINISTRATIVE SUPPORT

Administrative and operational support for the IBC is provided by the IBC Coordinator. The following duties are responsibilities of the IBC Coordinator:

1. Determine exemptions of research protocols and non-regulatory review.
2. Take minutes of the IBC meetings and maintain appropriate records;
3. Advise faculty, staff and students in preparation of protocol applications;
4. Provide education and program guidance to the University community regarding the IBC;
5. Receive all protocol submissions, including new, modified and renewed protocols;
6. Ensure each Member receives agenda and protocol applications with sufficient time for review prior to meetings;
7. Maintains a database of IBC approved protocols, annual reviews and disapproved protocol;
8. Maintains the IBC membership roster and update roster information;
9. Maintain the registration of the IBC with the NIH Office of Biotechnology Activities;
10. Communicate reviewer’s requests to PIs for additional information and revisions and review responses; and
11. Send notifications to PIs 30 days and 60 days prior to protocol expiration dates.

8. EXTERNAL REVIEW

The University IBC is capable of conducting reviews or assessments for external entities that fall within its level of expertise on a fee for service basis. External entities receiving funding from NIH and performing activities involving recombinant or synthetic DNA are subject to the NIH Guidelines and are required to register their IBC of record.

9. RECORD RETENTION

ORC maintains submission documents (new, renewals, modifications, etc.) and all related supplemental materials for a minimum of three years after the protocol is closed. Meeting agenda, minutes, and IBC Member rosters will remain on file in ORC as a permanent record of the committee’s activities. A curriculum vitae or resume of active Members of the IBC will be maintained in the ORC and will be updated in content as necessary. Policy guidance and forms will be disseminated from and stored in ORC until replaced by new and/or revised documents.

The PI is responsible for maintaining project data according University requirements and/or the terms and conditions of any sponsor, key personnel vaccination completion and declination records, and key personnel training records. The PI must store these records in a secure location.
10. CONFLICT OF INTEREST

A conflict of interest arises when financial, professional, or other personal considerations compromise, or have the appearance of compromising, an individual’s judgment in the review, design, conduct, or reporting of research. Activities involving biohazardous materials are subject to the University Policy 1110 - Interest and Commitment Policy.

10.1. PI Conflict of Interest

If a PI has disclosed a potential conflict of interest related to activities involving biohazardous materials, the IBC Coordinator will refer the case to the University Conflict of Interest Officer. The Conflict of Interest Officer will refer the case to the University Conflict of Interest Committee as appropriate. The Conflict of Interest Committee will review the disclosure, and consider the potential conflict of interest. The IBC Coordinator will collect the information necessary to fully inform the IBC of any proposed management plans. The IBC will carefully consider specific mechanisms to minimize the potential adverse consequences of the conflict.

10.2. Member Conflict of Interest

A Member must not provide review or vote on an application if they are an investigator on the application or have any other conflict of interest with any person or entity connected to an application. The Member must make any conflict of interest known to the IBC through the IBC Chair and/or IBC Coordinator. The Member is not required to identify the exact nature of the conflict of interest. The fact that an application is submitted by another PI from the Member’s department or area does not, in and of itself, constitute a conflict of interest.

The Member with conflict may participate in the discussion to answer the IBC’s questions regarding the application under review to the same extent as any PI may provide to the IBC. The Member will be recused for the IBC’s deliberation and vote. Failure to abide by these provisions may be cause for removal of a Member from the IBC.

11. REQUIREMENTS FOR ALL PROTOCOL SUBMISSIONS

11.1. CITI Training

The IBC requires all key personnel to have successfully completed applicable biosafety training in the Collaborative Institutional Training Initiative (CITI) online training program. Key personnel will need to register and affiliate their account with the University. Information about CITI including registration, training requirements, and FAQ can be found on the ORC website.
11.2. Signatures
The protocol application must be signed by the PI before any submission will be approved. The signature page may be mailed, emailed as a PDF, or brought to the ORC office.

11.3. Complete Protocol
In order for the application to be processed, it must be typed and include all supplemental materials. Incomplete or poorly prepared applications may be returned to the investigator before they are reviewed.

12. DEFINITIONS

12.1. Biohazardous material
An infectious agent or biological material presenting a risk to the health of humans, animals, or other forms of life such as: certain types of DNA, recombinant DNA and synthetic nucleic acid molecules; bloodborne pathogens; infectious organisms and viruses; select agents; and biological toxins.

12.2. Biosafety Levels (BSL)
Biosafety Levels are guidelines to safely handle biohazardous materials based upon the material’s Risk Group, activities being performed, facility construction and design, engineering controls, administrative controls, and personal protective equipment. Overviews of the levels are provided below and originate from “Biosafety in Microbiological and Biomedical Laboratories”.

BSL-1
BSL-1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required, but may be used as determined by appropriate risk assessment. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must be supervised by a scientist with training in microbiology or a related science.

BSL-2
BSL-2 builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that: 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in
which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

**BSL-3**
BSL-3 is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures. All procedures involving the manipulation of infectious materials must be conducted within BSCs or other physical containment devices.

**BSL-4**
Biosafety Level 4 is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments, or a related agent with unknown risk of transmission.

12.3. **Recombinant DNA (rDNA)**
Molecules constructed outside a living cell by joining natural or synthetic DNA/RNA segments to DNA/RNA molecules that can replicate in a living cell.

12.4. **Risk Groups (RG)**
Risk Groups are used to categorize biohazardous materials based upon their relative pathogenicity to healthy adult humans. Below are the NIH Guidelines definitions.

**RG-1**
Agents that are not associated with disease in healthy adult humans

**RG-2**
Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available

**RG-3**
Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (high individual risk but low community risk)

**RG-4**
Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available (high individual risk and high community risk)
12.5. Select Agents

Select Agents are biological agents or toxins that have the potential to pose a severe threat to public health and safety (CDC) or to animal health and safety, plant health and safety, or to the safety of animal or plant products (USDA). CDC and USDA maintain lists of agents falling under the Select Agent laws and regulations.