Idaho State University

Institutional Biosafety Committee (IBC) Handbook

GUIDELINES FOR THE OVERSIGHT AND USE OF RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES AND POTENTIALLY BIOHAZARDOUS OR INFECTIOUS MATERIALS IN TEACHING, OUTREACH AND RESEARCH

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Version 14, August 2021

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ISU IBC Handbook FY22.pdf

I. Authority and Purpose

A. Introduction

The Idaho State University (ISU) Institutional Biosafety Committee (IBC) is a committee appointed by the Vice President for Research. This ISU Institutional Biosafety Committee Handbook is your reference document detailing the policies and regulations governing research, teaching and outreach activities with biological materials. The instructions and information contained in this handbook are set forth and adopted by the ISU IBC and are based on federal, state, and local regulations and guidelines. Sections of the handbook describe and explain the various aspects of the review process and regulatory requirements. Investigators and IBC members should familiarize themselves with the contents of this handbook.

A successful biosafety program depends on investigators who are committed to a safe working environment and who are knowledgeable of the intricacies of laboratory safety. To assist, the services and resources of the ISU Biosafety Officer (BSO) and the Department of Environmental Health & Safety (EH&S) are available.

The IBC has the authority and obligation to stop any activity using biological materials, including but not limited to recombinant DNA and infectious organisms that the committee believes to be unsafe.

B. The Institutional Authority Under Which the IBC Is Established

The Idaho State University Institutional Biosafety Committee (IBC) is a university committee, reporting to the Vice President for Research, who serves as the Institutional Official (IO).

C. Scope of Authority Defined

The ISU IBC has jurisdiction over all research involving rDNA and regulated or other potentially biohazardous materials*, thereby providing broader protection than required by federal or state regulations.

The IBC has the authority to:

- Approve, request/require modifications to, or disapprove all research, teaching, field studies or outreach activities (irrespective of funding status or source) as specified by both the federal regulations and Institutional policy and based upon consideration of biological safety aspects
- Require progress reports from investigators
- Oversee the conduct of the study and training of study personnel
- Suspend or terminate approval of a study

*The phrase "potentially biohazardous material" is used throughout this handbook to indicate

all biological (biohazardous and infectious) materials that the IBC oversees. The list of these materials includes some that are not included in the NIH Guidelines and other materials that may not traditionally be considered biohazardous. In addition to regulation of activities with potentially biohazardous materials, the ISU IBC also oversees work with some organisms not viewed as biohazardous, including genetically modified whole plants which are commercially available and do not require APHIS permits. See also, **Section IX. Definitions**.

D. Purpose of the IBC

The IBC oversees and establishes University policy for review and approval of all activities involving the use of recombinant DNA and potentially biohazardous materials to assure compliance with current regulations and guidelines. Principal Investigators (includes principal instructors, hereafter called "PI") at Idaho State University who either store or carry out research or activities involving potentially biohazardous materials must inform the IBC via the Biosafety Protocol Registration Form. It is the practice of the University that all activities involving potential biohazards be conducted in a safe manner in order to protect laboratory workers, students, other persons, our community and the environment from potentially biohazardous agents or materials. Further, activities with biohazardous materials must be conducted in such a manner that projects pursued by one faculty member will not have an adverse effect on adjacent projects conducted by other scientists.

The ISU IBC will maintain all required records for 3 years after the completion of the activity.

E. Research and Activities Requiring Review and Approval from the IBC

The IBC reviews and approves many areas of biologically-related activities, including research, teaching, field studies and outreach activities.

The ISU IBC defines potentially biohazardous materials to include all infectious microorganisms (bacteria, fungi, parasites and viruses) and prions which can cause disease in humans, animals, or plants, or cause significant environmental or agricultural impact. The IBC will also capture information on materials that may harbor infectious organisms, such as human or primate tissues, fluids, cells, or cell cultures.

IBC approval is required prior to initiating projects and laboratory courses involving material(s) included in, but not limited to, any of the categories of potentially biohazardous materials listed below.

- Synthetic or recombinant nucleic acid molecules, including recombinant DNA
- Genetically modified organisms (GMOs) including but not limited to:
    - Animals (vertebrate and invertebrate), plants, and/or other organisms (bacteria and viruses) created and/or acquired and used by ISU employees in/on ISU

property or at associated field study sites;

- Transgenic field trials involving any GMOs to be introduced into the environment, including planting of deregulated items in the field (by ISU personnel and on ISU property or at associated field study sites);
- Field testing of plants engineered to produce pharmaceutical and industrial compounds.
- Pathogens/infectious agents (human, animal, plant, and other);
- Human & non-human primate cells (including all cell lines), tissues, blood and blood components, and other potentially infectious fluids
- Work with animals or vectors known or suspected to be reservoirs of Risk Group 2 (RG2) or RG3 infectious agents when such work increases potential exposure risks to personnel or other animals
- Oncogenic viruses used in conjunction with animals
- Nanotubes and nanoparticles
- Organisms or agents requiring federal permits (including but not limited to, APHIS, CDC, EPA, FDA), including:
- Select/Biological Agents and Toxins (CDC and USDA). Please note that possession, use, or transfer of Select/Biological Agents and Toxins entails additional requirements – contact the Office for Research Outreach and Compliance for additional information.

The IBC also serves as an advisory committee for University projects that involve possible biohazards that do not appear to fall into one of these areas. When it is unclear whether a material constitutes a potential biohazard, consult the IBC. Direct questions to the IBC Chair or the ISU Biosafety Officer.

No work should be considered so important that it jeopardizes the well-being of the worker or the environment. The planning and implementation of safety protocols to prevent laboratory-acquired infections and to eliminate the spread of contamination must be part of every laboratory's routine activities and biosafety manual. The handling of biological agents and recombinant DNA requires the use of precautionary measures dependent on the agents involved and the procedures being performed.

F. Principles that govern the IBC (Primary References)

The IBC developed this handbook and operates based upon the following regulations and guidelines:

- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), most current edition
- Biosafety in Microbiological and Biomedical Laboratories (BMBL), most current edition, developed by the Center for Disease Control (CDC) and the National Institutes of Health (NIH)
- U.S. Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS)7 CFR Part 340, Introduction of Organisms and Products Altered or Produced Through Genetic Engineering [also All APHIS Permit regulations/guidelines] this guidance and background on its applicability can be found at USDA APHIS | Biotechnology Regulatory Services (BRS)

USDA and the Department of Health and Human Services share joint responsibility for the oversight of select agents and toxins. Within those two agencies, APHIS and the Centers for Disease Control and Prevention (CDC) manage the Federal Select Agent Program (FSAP), which oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products.

The current Federal Select Agent Program site lists Select Agents and Toxins, exclusions and permissible toxin amounts. Found at https://www.selectagents.gov/sat/index.htm

Select Agents Regulations

7 C.F.R. Part 331: Agriculture

9 C.F.R. Part 121: Animals and Animal Products

42 C.F.R. Part 73: Public Health (CDC)

G. Materials and activities requiring additional permits or approvals

In general, any biological material that requires a federal permit should be registered with the ISU IBC via the Biosafety Protocol Registration Form. Provide copies of the permits with this Form. Permits that require the signature of the IO include:

a. Federal permits

Many biological materials and activities require additional federal permits. These permits may be necessary for a wide range of activities, including:

- APHIS permits (through USDA APHIS | Organisms and Vectors Guidance & Permitting).
    - Field trials of genetically modified organisms (http://www.aphis.usda.gov/brs/pharmaceutical.html)
- CDC permits (http://www.cdc.gov/od/ohs/biosfty/biosfty.htm).

FDA permits

- EPA permits

b. External university protocols and participants

When an ISU PI seeks to join a biosafety project at an institution other than ISU, ISU IBC approval is still needed. In lieu of the ISU protocol form, the other institution's IBC protocol approval letter and the protocol may be provided to the ISU IBC for consideration. The external protocol must include a description of the specific activities planned for the ISU PI on the project.

The IBC Chair has the authority to accept the external protocol approval and issue approval to the ISU PI. If accepted, the IBC CC will distribute the ISU approval. The protocol will be available for the ISU IBC members to review.

Alternatively, the ISU IBC Chair may ask for a full ISU protocol, with a regular IBC protocol review and vote.

Biosafety projects involving non-ISU personnel (including students enrolled at other universities not employed by ISU) must include these people as personnel listed on the ISU IBC protocol documents.

Additional assurances, material transfer agreements (MTAs), Authorized Volunteer Services Agreement forms may also be required. Contact the ISU IBC as soon as possible when working with non-ISU personnel to ensure a complete review prior to the start of work.

H. Membership of the IBC

Number of members

The IBC will have no less than five members with varying backgrounds to promote complete and adequate review of research, teaching, and outreach activities involving potentially biohazardous materials and rDNA commonly conducted at ISU.

Qualifications and Diversity of members

The IBC will have sufficient expertise among its members to be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, recognized guidelines, applicable laws, and standards of professional conduct and practice. The IBC will promote respect for its advice and capability to assess the safety of research, teaching and outreach activities involving recombinant DNA of other biohazardous materials, and to identify any potential risk to workers, public health, or the environment. The makeup of the IBC will meet the requirements of NIH-OSP.

As needed for specific projects, at least one member (appointed or ad-hoc) whose primary expertise is in plants, plant pathogens, and plant pest containment principles will contribute

said expertise to the IBC. One member with expertise in animals and animal containment principles will be appointed to the IBC, or the IACUC Chair will provide protocol consultation as needed.

The Institutional Biosafety Officer (BSO) will be a voting member of the IBC. This role is fulfilled currently by the head of the Environmental Safety and Health office or division.

The IBC will include at least two voting members from the surrounding community. Neither of these members will be affiliated with Idaho State University and both shall represent the interest of the surrounding community with respect to health and the protection of the environment.

Other non-ISU members are permitted, but are not required, to serve as voting IBC members if their experience and expertise are deemed beneficial to the committee. These persons may be proposed to the Vice President for Research for appointment with the same requirements as all other voting members.

A member of the ISU Facilities Services staff of the Maintenance division will serve as a non-voting member to support IBC understanding of operational, laboratory and waste considerations. This person will report on any relevant findings of the State Building Inspector.

II. IBC Membership (Rules)

A. Appointment and Removal

All IBC members are appointed by the Vice President for Research as ISU's Institutional Official (IO). When the IBC Chair and/or individual IBC members propose a potential new member, the Chair or his/her designee will contact the proposed member to ensure their interest. Following this contact, the Chair or the IBC Coordinator will provide the proposed member's curriculum vitae or resume plus contact information to the full IBC for a vote. If the majority vote in the affirmative, the candidate's information is sent to the Vice President for Research (VPR) who will formally offer the position to the candidate and issue an appointment letter.

The Chair

Appointment

The Chair is appointed by the Vice President for Research (IO). The Chair serves for at least one year and may be reappointed. The Chair is also a voting member, counting toward the quorum at meetings. If the Chair is unavailable for a scheduled meeting, any member may be asked by the Chair to be a substitute. If a Chair is unavailable for a period of time exceeding 3 months the Institutional Official may appoint a temporary Chair. The temporary Chair will act until the end of the term of the previously appointed IBC Chair.

Removal

The Chair may be removed or replaced by the IO. This action shall be based on one or more of the following:

- written request of the majority of the committee members for behavior disruptive to the work of the IBC, or
- documented non-participation (refusing to vote when no conflict of interest exists), or non-attendance (more than two meetings per semester without cause), or
- for non-disclosure of a known conflict of interest related to protocols reviewed by the IBC.

IBC members

Appointment

The Vice President for Research appoints members. Members appointed to the IBC will serve on the committee for a three-year term. Appointments typically **start** with the beginning of the academic year (August 16th of the year appointed) and **end** August 15th three years later. There is no limit to the number of terms a member may serve on the IBC.

Removal

IBC members may be removed or replaced by the IO, in consultation with the IBC Chair. This action shall be based on one or more of the following:

- written request of the majority of the committee members for behavior disruptive to the work of the IBC, or
- for documented non-attendance (more than two meetings per semester without cause), or for non-participation (refusing to vote), or
- for non-disclosure of a known conflict of interest related to protocols reviewed by the IBC.

B. Training of IBC Chair and Members

Orientation

A new member orientation, including introduction to the federal regulations, ISU IBC meeting procedures, review process, and the IBC Handbook with forms, will be conducted by the Chair and/or IBC Coordinator. The Assistant Vice President for Research Outreach and Compliance (ROC) will conduct training when a new IBC Chair is appointed.

Continuing Education

Continuing education of the IBC member is done through special training meetings as well as educational information distributed to members through newsletters, on-line courses, or by discussion at a full committee meeting. At a minimum, this training will occur once a year.

Reference Materials

The ISU Institutional Biosafety Committee, PIs and Researchers should use the resources listed in section *I. Authority and Purpose, E. 1. Principles that govern the IBC (Primary Reference)*.

It is assumed that IBC members, PIs and others using potentially biohazardous materials will become familiar with the relevant federal guidance and regulations related to biosafety and biohazardous materials, such as the BMBL. These substantial documents are available online and will not be printed for the use of the IBC or individual researchers. This handbook includes some urls, but no hyperlinks to extend its effective life.

C. Use of Consultants

The ISU IBC is encouraged to use non-member consultants for advice and information in specialized areas as needed. These consultants may be ISU faculty or staff, or unaffiliated with ISU. The consultants may present their assessments in writing or in person.

D. Conflict of Interest

No IBC Committee may have a member participate in the IBC's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IBC. IBC members who are directly involved (e.g., as investigators or faculty sponsors) in a study being reviewed by the IBC will absent themselves from the meeting room (or mute the audio if participating by telephone, video, or computer link) during the committee's discussion of and voting on that study.

Examples of such conflicts of interest could include: a member of the IBC who serves as an investigator or faculty advisor on research under consideration by the IBC; or a member who holds a significant financial interest (as defined in the University's Policy on Conflicts of Interest and Commitment) in a sponsor or product under study.

E. Compensation and Liability Coverage

1. Compensation

IBC members are not compensated for their IBC participation.

2. Liability coverage

IBC members function as employees or agents of Idaho State University. As such their actions are covered by the ISU liability coverage if taken within the course and scope of their employment or agency. This means that they are covered when performing within the course and scope of their IBC responsibilities. Unaffiliated members of the IBC are also covered by ISU liability coverage when performing within the course and scope of their IBC service.

III. Duties and Responsibilities

A. The Institutional Biosafety Committee (IBC)

The IBC, under the direction of the IBC Chair, is responsible for reviewing and approving practices and protocols for the handling of recombinant DNA and potentially biohazardous materials at all research facilities (including field activities) under the auspices of Idaho State University. This includes requesting changes to meet requirements as needed plus initial and periodic inspection of labs and facilities as determined by risk level of the project. The IBC also assists EH&S in the development and review of policy involving potentially biohazardous agents.

The IBC function and composition fulfills regulatory requirements. It is comprised of faculty representatives from various academic disciplines and campuses at ISU, researchers and community representatives not affiliated with the university. The Committee meets on a regular basis during the academic year to review research activities and proposals submitted to the IBC. IBC maintains a listing of BSO-approved biosafety laboratories.

The Institutional Biosafety Committee can be reached through the Office for Research Outreach & Compliance at (208) 282-1336 or via biosafe@isu.edu.

B. IBC Chair

The Chair conducts all IBC meetings in accordance with institutional and federal requirements. They work closely with IBC members, the IO, BSO and PIs, instructors and researchers to ensure that research and activities involving regulated or potentially biohazardous materials are conducted safely and in accordance with all applicable federal, state and institutional regulations, policies and procedures. The Chair is the designated signatory for the IBC.

The Chair may delegate signatory duties to the Assistant Vice President for Research Outreach and Compliance (ROC).

The IBC Chair will report in writing within 10 working days to the Vice President for Research, relevant Unit or Agency Head (sponsor), any applicable regulatory body, any occurrence of adverse events as mandated in the Federal Regulations. Select Agents and Toxins require immediate notification of the Responsible Official (the Vice President for Research) and the relevant agency (CDC or USDA/APHIS).

C. IBC Members

- Ensuring Research Compliance
- ISU IBC members are responsible for ensuring that all research and other activities utilizing regulated or potentially hazardous biological materials are reviewed and approved in a manner consistent with federal, state, and local laws, regulations, guidelines and institutional policies.

- Conducting initial and continuing protocol reviews

Members are responsible for reading submitted/proposed protocols and related emails, and for attending and actively participating in IBC meetings, in person or remotely. Materials are reviewed prior to the meetings in preparation for a vote on the specific protocol application. Additionally, use of a shared web-hosted repository may be expected, unless an accommodation is required.

- Protocol discussion

IBC members will actively participate in discussion of protocols and laboratory manuals and other IBC issues during scheduled meetings. Should a member not be able to attend a scheduled protocol review meeting, they are encouraged to provide their observations in advance via the biosafe@isu.edu email account or other centralized method established for the IBC.

Absent members' observations will be read into the meeting record by the IBC Compliance Coordinator, adding to the information considered prior to a vote. Absent members may not vote on a protocol.

- Maintaining Confidentiality and Avoiding Conflicts of Interest

As part of their acceptance of an IBC appointment, members must sign a combined Confidentiality and Conflict of Interest Agreement related to the research data and details which protocol review entails. Community/Non-Affiliated Members must also sign an ISU Volunteer Authorization Form to document their understanding that their membership role does not provide employment protections.

- Determine study review cycle

The IBC requires that all active protocols be resubmitted every three years, unless the IBC has determined the nature and/or risk of the research requires a more frequent renewal. For example:

All field trials that require an APHIS permit or notification require an annual submittal of the current USDA permit or notification to the IBC.

- Review and approval of protocol changes, modifications or renewals

The IBC reviews and votes to approve, defer or disapprove all requested changes (modifications) to currently approved research or activities prior to their implementation by the PI.

The IBC also reviews and votes to approve, defer or disapprove all protocol renewal applications.

The instructions for completion of either process appear in **Section VIII. Principal**

Investigator/Instructor Protocol Submissions of this Handbook with the forms available online at the Biosafety webpage.

D. ISU Biosafety Compliance Coordinator (IBC CC)

The IBC CC is a critical, non-voting member of the IBC.
The IBC CC performs the following duties:

Performs initial administrative review of all biosafety applications and assigns protocol identification numbers.

Maintains the list and curriculum vitae of IBC Members and submits this information annually to the NIH-OSP.

Works with the Chair to prepare meeting agendas.

Takes meeting notes, prepares minutes.

Reports IBC findings and requested actions to the investigator.

Communicates with PIs, conveying IBC requests for information, protocol revisions and review responses.

The IBC CC drafts, and the IBC Chair signs, a letter addressed to the PI following full committee vote documenting the approval, deferment or disapproval of a protocol.

Maintains all biosafety documents for a minimum of three years after project completion.
Maintains lists of submitted, approved, deferred and disapproved applications.

Maintains all records related to IBC activities, including a document repository, forms, manual.

Maintains the ISU IBC website information.

Facilitates communications between investigators, IBC members and institutional officials.

E. The ISU Biosafety Officer (BSO)

The BSO is a voting member who

- Develops, leads, directs, and manages a comprehensive biological laboratory safety program for Idaho State University.
- Reviews laboratory biosafety manuals and standard operating procedures (SOPs) for compliance with guidelines for BSL and ABSL procedures
- Reviews research protocols, providing general guidance about health and safety standards
- Assists PIs in the development of appropriate project-specific biosafety laboratory manuals for all activities using potentially biohazardous materials.

- Performs (or coordinates and approves) biosafety laboratory facility and containment equipment inspections against the applicable regulatory requirements, based on biomaterial type. No biosafety protocol will be approved for a project start until the laboratory involved passes a biosafety inspection.

Laboratory inspection review procedures are developed in coordination with the IBC in compliance with CDC guidelines for research and diagnostic laboratories based upon their Biosafety Level (BSL) or with their Animal Biosafety Level (ABSL). For plant material biosafety inspections, follow the USDA/ARS guidance.

Inspections for BSL-1 and BSL-2 laboratories are conducted initially and at 3 year intervals, if protocols are to be renewed. Should a BSL-3 lab be established, it will be inspected initially and annually thereafter by the BSO.

The BSO maintains an Inspection Record that lists the approved biosafety laboratories with review dates and results.

The BSO coordinates with Facilities Services to identify corrections, modifications and repairs required for safe operations of laboratory physical facilities. For USDA/ARS regulated biosafety laboratories or facilities, the BSO acts as the Research Safety Programs Officer (RSPO) in accordance with USDA/ARS 242.1M, Appendix 9A, *Project Team Roles and Responsibilities as They Relate to Biological Safety Issues.*

IV. Duties and Responsibilities of Researchers

A. Principal Investigators

A Principal Investigator (PI) is defined as an ISU faculty member who is responsible for the conduct of a biosafety protocol in a research laboratory, field setting or teaching laboratory and the supervision of its associated personnel. Students, including undergraduates, graduate students and post-doctoral fellows, may not serve as PI on a Protocol.

PI Responsibilities

- Be familiar with this Handbook, the IBC forms and applicable regulations
- Register the potentially biohazardous agents they propose to use with the IBC
- Prepare a protocol and the project-specific biosafety laboratory operations form for the individuals and activities under their purview for review and approval by the IBC prior to commencing work with biological or potentially biohazardous materials for a project. See Section VIII. Principal Investigator Protocol Submissions for instructions.
- Perform risk assessments (and develop plans for all activities accordingly)
- Ensure that all project personnel (including the PI) complete or are current on the applicable CITI training prior to the start of work. Complete CITI Biosafety and Biosecurity training modules specified on the applicable project forms.
- Periodically evaluate all laboratory operations
- Cooperate with BSO biosafety laboratory inspections
- Establish the appropriate biological safety containment levels for their lab by consulting the BSO
- Ensure strict adherence by lab staff and students to biological safety practices and techniques for all work involving potentially biohazardous materials
- Ensure that personnel receive the appropriate training on the potential hazards and precautionary measures applicable to the potentially biohazardous materials. This includes instruction in specific practices and techniques required for safely handling the agents identified in protocols
- Coordinate with EH&S for the appropriate disposal of biohazardous and related biological materials

B. Unit Leaders (Deans, Chairs, and Directors)

Unit leaders (Deans, Chairs, and Directors) have the following responsibilities:

- Determine that appropriate facilities and safety equipment are available for proposed research or instruction involving potentially biohazardous agents *and* provide funds to complete any required facility modifications, corrections or repairs identified as necessary during an ongoing project
- Require that prior to initiation of research, each PI or laboratory director planning to use recombinant DNA or potentially biohazardous material completes and submits the IBC Biosafety Protocol Registration Form
- Require that students receive instruction in safety procedures in teaching and research laboratories or field situations where the potential for exposure to a potentially biohazardous agent or material exists
- Provide leadership and support in laboratory safety at the management level in the unit

C. Laboratory Workers, Postdocs, Students, Individuals

Persons who work in the laboratory in a technical (rather than purely administrative) capacity are defined as a laboratory worker, whether the person is a faculty member, student, intern, visiting scholar, or volunteer. Laboratory workers are the most critical element in maintaining a safe working environment. Individuals must adhere to biological safety practices and techniques. This includes working with potentially biohazardous agents using the appropriate containment and personal protective equipment as directed by their supervisor and PI.

It is the laboratory worker's responsibility to:

- Conscientiously follow lab-specific biosafety practices and procedures
- Complete and maintain current status of CITI Biosafety training as applicable to your current project(s)
- Inform the PI of any health condition that may be a result of or complicated by their work in the lab
- Report to the PI or the lab supervisor all problems, procedural discrepancies, spills, or accidental releases as soon as they occur
- Report to the Office for Research Outreach and Compliance any significant violations in biosafety policy, practices, or procedures that are not resolved by the PI
- Refuse to take any adverse action against any person for reporting real or perceived

problems or violations of procedures to supervisors, the PI, the Office for Research Outreach and Compliance or members of the Institutional Biosafety Committee.

D. The ISU Department of Environmental Health and Safety (EH&S)

The ISU EH&S department supports research and other activities involving biological materials in areas of laboratory biosafety, public health, and occupational biosafety.

The EH&S:

Maintains programs and educational materials pertaining to laboratory safety

Performs laboratory inspections under the direction of the BSO, when needed

V. IBC Operations

A. Independence from Other Committees

The IBC functions independently of other committees and makes its determinations whether to approve, disapprove, suspend or terminate a protocol based upon whether or not biological safety aspects adhere to relevant regulations, guidelines and policies.

B. Conducting Initial and Continuing Reviews

The ISU IBC is responsible for the both the initial and continuing review and approval of all projects involving regulated or potentially biohazardous materials conducted under the auspices of Idaho State University regardless of funding source.

C. Protocol Renewals

The IBC requires that all active protocols be resubmitted every three years, unless the IBC has determined the nature and/or risk of the research requires more frequent renewal. All field trials that require an APHIS permit or notification require an annual submittal of the current USDA permit and notification to the IBC.

All triennial resubmissions must complete a full set of protocol documents and must utilize the most current versions of all IBC forms.

D. Project Changes Initiated Without IBC Review

Unless necessary to eliminate apparent immediate hazards, changes in approved research *should not be initiated* without IBC review and approval. There are situations where a serious or unexpected adverse event requires an immediate change to a protocol in order to relieve an apparent immediate hazard. In these situations, the PI may implement a change necessary to protect humans or the environment. Investigators must contact the IBC Chair or CC if this type of situation arises as soon as reasonably allowable.

E. Prompt Reporting of Unanticipated Problems

The IBC Chair will report in writing within 10 working days to the Vice President for Research, relevant Unit or Agency Head (sponsor), any applicable regulatory body, any adverse event as mandated in the Federal Regulations. Select Agents and Toxins require immediate notification of the Responsible Official (the Vice President for Research) and the relevant agency (CDC or USDA/APHIS).

F. Reporting the Misuse of Potentially Biohazardous Materials

Misuse of potentially biohazardous materials may be reported in person, on the phone, by email or written note to any of the following:

- Institutional Official (IO)
- Institutional Biosafety Committee (IBC) Chair
- Institutional Biosafety Officer (BSO)
- IBC Compliance Coordinator (IBC CC)
- any IBC member

Information concerning noncompliance or perceived noncompliance with the NIH Guidelines or University policies or procedures may be brought forward by any person and the IBC must recommend appropriate action.

In addition, concerns can be sent on-line through MySafeCampus.com. The MySafeCampus reports are sent to the Assistant Vice President for Research Compliance who then sends them to biosafe@isu.edu.

Reports may be made anonymously and by anyone, ISU-affiliated or not.

The IO, the IBC Chair and the IBC members follow the procedure described in IBC SOP 001 IBC Procedures for the Investigation and Reporting of Concerns Regarding Biological Materials Use, Appendix A of this Handbook.

VI. IBC Meetings and Decisions

A. Meeting Schedules

The full IBC will meet monthly, typically the third Tuesday of each month – from mid-August, through May. The Committee does not meet in June or July (summer).

Summer business, if essential to research progress, will be addressed by the IBC Chair on a case-by-case basis. Approvals that would normally require the full IBC review may be given provisional (interim) status and will be evaluated by the full committee at the August meeting.

Among other business, August meetings will include an introduction of new members, submission of completed IBC member COI and or Volunteer agreement forms, annual member training activities, and review of protocols provisionally approved during June and July.

The IBC Chair may decide to cancel meetings when there is no business. The IBC CC then posts a notice to the committee.

IBC meetings are open to the public (unless proprietary information is to be discussed, which will occur in executive session). Meeting dates for the current semester are published on the Research Outreach and Compliance Biosafety website.

B. Pre-meeting Distribution of IBC Review Materials to Members

Seven calendar days prior to a meeting the IBC CC will send notice to each committee member of the availability of the following in the IBC share folder (or as email attachments as appropriate):

- Meeting agenda
- Minutes from the previous meeting
- All new protocols to be reviewed
- Modification Requests
- Renewal Requests
- Continuing Education Materials

C. The Review Process

Overview of the review process

The ISU IBC is responsible for the review and approval of all projects involving potentially biohazardous materials conducted under the auspices of Idaho State University regardless of funding status (funded or non-funded) and funding source (external or internal). The IBC will consider all information presented via the Biosafety Protocol forms or the IBC Review Inquiry form. The IBC may request additional information and/or clarification from the PI. The IBC CC sends requests for additional information from the biosafe@isu.edu email account.

Pre-IBC review

Upon receipt of a protocol application, the IBC CC will check the documents for completeness of non-technical information: PI name, department, project name, etc.; and inclusion of protocol ID number if a modification. S/he will confirm training completion dates for all personnel. For new applications, once the document set is complete, the IBC CC will assign a protocol ID number and distribute all documents to the members.

Committee review

The IBC Chair will present the proposed protocols to the convened IBC; the Chair may delegate responsibility for these presentation to other IBC members. All committee members are expected to review all protocol documents before IBC meetings. All protocols will be discussed in detail at convened meetings.

The Committee will also review additional permits as needed, with their duration based on their regulating agency.

The IBC will review and discuss protocols and may make one of three determinations:

1. Approved:

The IBC may vote to approve the protocol as submitted. The PI will then receive an approval letter. The IBC approves most protocols for three years; some projects may require annual reviews. At the end of three years, PIs wishing to continue the previously approved protocol must submit a new set of protocol documents using the most current Biosafety Research Registration and Protocol forms for review by the full committee. This process is known as "third year renewal".

2. Deferred:

The IBC may vote to request protocol changes and/or submission of additional information. In this instance, approval is deferred pending submission and evaluation of the requested changes, information or other requirements by the IBC. The IBC CC will contact the PI requesting the additional information or to list the specific requirements to be completed prior to the IBC granting approval.

If the IBC determines the information or requirements needed are **minor**, then once the additional information or requirements are met, reviewed and accepted by Chair, the PI will receive the approval letter. If changes are considered **major**, the full IBC may require re-review at a convened IBC meeting prior to granting approval.

The IBC will maintain deferred protocols for 6 months to allow the PI to meet the requirements for approval. After 6 months, the IBC will issue a notice closing the project. The protocol will need to be resubmitted to the IBC.

3. Disapproved:

In certain cases, research activities may be proposed that are deemed too hazardous or for which the proper expertise or facilities are not available. In such cases the IBC may vote to disapprove the research.

Modifications to approved protocols

All modifications to currently approved protocols/activities are required to have IBC review and approval prior to implementation of the changes. Modifications are requested by use *Form E Modification of Approved Protocols*. **Modifications do not alter the expiration date of the original, approved protocol.**

There are two types of modifications:

a) Significant modifications

When researchers make significant changes to the scope, the materials or the processes in a protocol, a full IBC review is required. Examples of significant modifications include addition of a new class of bio-hazardous material not previously utilized, addition of materials requiring a higher biosafety level, or the addition of materials or processes that may increase the project's associated risks. The change of the PI is also considered a significant change. The PI is responsible for determining whether the planned modifications are extensive enough to warrant a wholly new protocol submission.

b) Minor modifications

The IBC Chair and the BSO (together) may approve Minor modifications.

Examples of minor modifications include the addition of very similar potentially bio-hazardous materials to those already listed on the approved protocol (where same conditions would apply in the lab) or a change of laboratory room (to an equivalent and approved facility).

- The IBC Chair may independently approve additions of personnel or changes of contact information on the protocol without other member review.

Advanced project initiation

When a PI provides the required forms together with a written request and justification for project initiation in advance of protocol approval, the IBC takes these steps:

1. A subcommittee of the IBC Chair and the BSO will review the protocol and the justification for advance initiation. Early project initiation may be approved, deferred or disapproved.

2. If approved, the work may begin AND there will be a recommendation for an approval vote during the next IBC meeting.

3. If the subcommittee does not approve advanced project initiation, no project work may begin at that time and the protocol will be considered during the next scheduled IBC meeting.

No requests for early project start will be considered without a complete protocol document set.

Protocol suspension or termination of approval

The ISU IBC has the authority to suspend or terminate approval of research if it

- is not being conducted in accordance with its approved protocol or
- has been associated with unexpected serious consequences.

Suspension of any protocol requires a majority vote of the full committee, except when determined that a health or safety issue exists – then the IBC Chair may issue suspension notice.

Any suspension or termination of approval shall include a statement of the reasons for the action of the IBC. The suspension or termination of approval shall be reported promptly to both the PI and their unit head.

Post-meeting communication

IBC actions that occur during meetings are promptly conveyed (usually within 5 working days) to the PI in writing by the IBC CC. Communications include notification of project approval, deferment due to IBC request for changes or new information, or disapproval. For deferred protocols, all requirements that must be met for the committee to grant approval are detailed.

D. Voting Requirements

1. Quorum required

A quorum of more than half of the voting membership is required to conduct business.

2. Full voting rights of all reviewing members

Each member has one vote.

3. No absentee votes

No absentee votes are allowed.

4. Prohibition of conflict-of-interest voting

IBC members must not vote on a protocol if they are investigators on the protocol or have any other conflict of interest with any person or entity connected to a protocol.

5. Alternates

Each IBC member may have designated alternates, who are appointed by the IO. Alternates may attend all meetings, however, they vote only when the primary member is absent. Alternates attending meetings (when the primary member is present) do not count toward quorum and may not vote. Alternates are encouraged to review all protocols and participate in all discussions.

VII. IBC Record Requirements

A. IBC Membership Roster

Each year the IBC Compliance Coordinator will submit to NIH-OSP (Office of Science Policy) a copy of the membership roster and curriculum vitae demonstrating the qualifications of each committee member.

B. Written Procedures and Guidelines

Written IBC procedures and guidelines are contained in the ISU Institutional Biosafety Committee (IBC) Handbook. For a copy of this handbook, please visit the Biosafety website or contact the IBC Compliance Coordinator (208) 282-1336, (biosafe@isu.edu) to request a copy.

C. Minutes of Meetings

The IBC CC will take minutes at each meeting of the IBC. The minutes will contain:

Members present

Others present (guests/consultants/researchers)

Protocols presented

Summary of discussions

Motions made and seconded

Record of voting

List of the NIH Guideline-covered protocols under discussion

Assurances that the current OSP Guidelines are adhered to

Summary of other IBC matters discussed

D. Retention of Records

All protocols reviewed and related materials will remain on file in the Office of Research Outreach and Compliance (ROC) for three years after conclusion of the research. The IBC maintains a database of all proposed and active projects and activities involving rDNA and potentially biohazardous material. Files may be paper or electronic. Meeting minutes and IBC rosters will remain on file at ROC as a record of the committee's activities. Policy guidance and forms will be disseminated from and stored by ROC until replaced by new and/or revised documents.

E. Contacting the IBC

The Biosafety Protocol forms are available from the ISU website under Biosafety within the Office for Research webpage. Any questions regarding IBC review or the content of this handbook should be directed to the IBC Chair via (208) 282-1336 or biosafe@isu.edu. The IBC Chair keeps in contact with researchers regarding IBC decisions and requests for additional information. The public may address comments to the IBC by addressing the Chair or using the same phone and email account. If these communications include comments on IBC actions, those comments (and IBC response) will be forwarded to NIH Office of Bio-technology Activities as specified in Section IV-B-2-a-(7) of the NIH Guidelines.

VIII. Biosecurity

The security of biological materials is of significant concern and importance. The PI and all laboratory personnel must be conscientious with respect to the control of biological materials. Access to laboratories and materials must be limited to the greatest extent possible. PIs should identify the risk that a material may pose (i.e,. low, medium, high) and perform a vulnerability assessment of the use and storage of the material. The protection and security of the material should be based upon the risk. Security measures to be considered for biological materials include (but are not limited to):

- Additional locks (padlocks and electronic access cards) on laboratories, freezers, etc. where biological agents are used or stored.
- Chain-of-custody forms within laboratories to track materials.
- Inventories of biological materials.
- Logs of access to areas where biological materials are in use.
- Conduct a threat and/or vulnerability assessment.

When materials will be transported to another country, export controls requirements should be addressed prior to shipping. Address questions to the Assistant Vice President for Research Outreach and Compliance who is ISU's Export Control Officer.

IX. Principal Investigator/Instructor Protocol Submissions

A. Protocol Submission and Approval Cycle

- Who submits a Protocol

The Principal Investigator (see definition) for the project submits the Protocol Registration and relevant IBC forms. Students, including undergraduates, graduate students and post-doctoral fellows, may not serve as PI on a Protocol.

- Timing for protocol submission

Protocols must be submitted at least fourteen (14) business days in advance of a scheduled IBC meeting to be considered for a vote during that meeting. Protocols should be submitted well in advance of the planned research start date. Protocols received less than 14 days before a meeting may be held until the next monthly meeting.

Refer to the Biosafety webpage for the submission deadlines and meeting dates (under Research Outreach & Compliance). IBC does not regularly meet in the summer.

Submit protocols for summer work no later than the submission deadline prior to the April meeting.

- Period of protocol approval / expiration cycle

The ISU IBC approves most protocols for up to three years. An expiration date is set and conveyed within the approval letter.

- Renewals

If the PI wants to continue their work beyond the expiration date, a new set of protocol documents must be submitted for IBC consideration of a renewal. Use the most current versions of the ISU Biosafety Project Registration and protocol forms to apply for renewal. See **Section IX. Principal Investigator/Instructor Protocol Submissions** information below.

- Progress reports and IBC oversight

All approved biosafety teaching or research protocols are subject to continuing IBC review, as well as periodic review by the IBC. The period of review is set at the time of IBC approval. Periodic reports on research progress may be requested at the discretion of the IBC.

- PI Request for Advanced Project Initiation

A PI may request permission to initiate a project prior to IBC review and approval. For this, a complete set of protocol documents and biosafety laboratory manual must accompany a written request with justification for early project initiation. The steps taken by the IBC to address this request are detailed above (**Section VI., C. The Review Process**). No work can be initiated until formal IBC approval is received.

- External university protocols and participants

When an ISU PI seeks to join a biosafety project at an institution other than ISU, the ISU IBC approval is still needed. In lieu of the ISU protocol form, the other institution's IBC protocol approval letter and the protocol may be provided to the ISU IBC for consideration. The external protocol must include a description of the specific activities planned for the ISU PI on the project.

The IBC Chair has the authority to accept the external protocol approval and issue approval to the ISU PI. If accepted, the IBC CC will distribute the ISU approval. The protocol will be

available for the ISU IBC members to review.

Alternatively, the ISU IBC Chair may ask for a full ISU protocol, with a regular IBC protocol review and vote.

Biosafety projects involving non-ISU personnel (including students enrolled at other universities not employed by ISU) must include these people as personnel listed on the ISU IBC protocol documents. Additional assurances, MTAs, Authorized Volunteer Services Agreement forms may also be required. Contact the ISU IBC as soon as possible when working with non-ISU personnel to ensure a complete review prior to the start of work.

B. Submissions

Protocol Submissions Overview

Submit protocol applications or IBC Review Inquiry Forms electronically to biosafe@isu.edu. The email subject line should refer to "protocol for review".

No work may be started before an approved protocol is in place.

The completion of the documents listed below requires use of the latest version of MS Word (2016 or later). PIs should avoid saving the entire protocol form file as a ”locked pdf version” in order to use electronic signatures.

At present, please print and hand-sign signature pages, then scan them with the other pages. This will allow the IBC CC to make minor amendments during check-in, such as assigning protocol IDs and receipt date.

- Required Documentation for all new applications and third year renewals

All submissions must include the Biosafety Project Registration form.

In addition, the following forms must be submitted as applicable:

1. A BSL1 Biosafety Laboratory Manual for the project laboratory(ies)

2. A BSL2 Project-specific Laboratory Operations Manual

3. A BSL2 laboratory self-inspection form, including an appointment for EHS Laboratory Inspection (PI must arrange with BSO).

4. Protocol-specific forms, including the following:

Protocol Form A Use of Recombinant or Synthetic Nucleic Acid Molecules in Research

Protocol Form B Use of Infectious Agents, Toxins and Select Agents in Research

Protocol Form C Human and Non-Human Primate Blood, Cell Lines, or Other Potentially Infectious Materials (OPIM)

Protocol Form D Use of Biological Materials in Teaching Laboratories

See also, Appendix B. Information for Completing Forms A – D.

Receipt by IBC Compliance Coordinator

The IBC Compliance Coordinator pre-reviews protocols and biosafety laboratory manuals for required signatures, checks completion of the forms and confirms training in CITI system when applicable. The IBC CC will contact the PI by phone or email requesting clarification, to provide assistance, as required. Incomplete form sets will not be distributed to the IBC for review.

After the application clears pre-review, the PI will receive an email from biosafe@isu.edu confirming receipt and assigning the protocol identification number (B-###).

Protocols are added to the agenda for the next scheduled IBC meeting with the documents distributed to the IBC members at least 7 working days prior to that meeting date.

The BSO is notified by the IBC CC of the need to schedule and perform a biosafety laboratory inspection, if feasible, prior to the meeting when the protocol status will be voted.

The Review Process

The ISU IBC is responsible for the review and approval of all projects involving potentially biohazardous materials conducted under the auspices of Idaho State University regardless of funding status (funded or non-funded) or funding source (external or internal).

The IBC will consider all information presented and may request additional information and/or clarification from the researcher. The IBC CC sends requests for additional information from the biosafe@isu.edu email account.

Details of the review process can be found in **Section VI., C. The Review Process** above and are summarized here.

The IBC Chair or the Chair's designee presents the proposed protocols to the convened IBC and protocols are discussed in detail. The Committee will also review additional permits as needed, with their duration based on their regulating agency.

After full discussion, the IBC will make one of three determinations:

a. Approved: The IBC votes to approve the protocol as submitted. The PI will then receive an approval letter.

b. Deferred: Approval is deferred when additional information is needed or other requirements must be met. The IBC CC will contact the PI requesting said information and detailing the requirements. The PI has up to 6 months to supply this information. After 6 months, the project application will be closed.

If the information or requirements constitute a major change to the protocol, the IBC may require re-review at a convened IBC meeting prior to granting approval.

If the IBC determines the information or requirements needed are minor, and once the additional materials are reviewed and accepted by Chair, the PI will receive the approval letter.

c. Disapproved: In certain cases research activities may be proposed that are deemed too hazardous or for which the proper expertise or facilities are not available. In such cases the IBC may vote to disapprove the research.

Post-meeting

Protocol documents are held until receipt of all requested changes or information is received. The PI answers are then either incorporated to the file, or the document modified to bring it in sync with the IBC direction. The original submission, the final protocol with the lab manual and the voting history are all maintained, with the associated email thread(s) as the file for the specific protocol.

Protocol files are maintained for a minimum of 3 years following the closing date of the approved protocol, or from the date the protocol is disapproved. Renewals of existing protocols maintain the entire record of the project as a single protocol under the same protocol identification number (ex: B####).

Protocol Renewals

Third year renewals require completion of a full set of new protocol documents as outlined above (**Section V., C. Protocol Renewals**). The most current versions of protocol documents must be used.

A PI may copy *the content* of previously approved forms so long as the details represent the current and ongoing work of the project. **Submit at least 3 months prior to expiration of existing protocol.**

An updated EHS laboratory inspection report, a self-inspection form for BSL2 work (within 60 days prior to the renewal application submission date) and an updated Certification signature page including all current project personnel including the PI, must be included.

Research projects previously approved by the ISU IBC may be subject to additional review by federal or state agencies.

Check the Biosafety website for the most current form versions. More detailed instructions on the submission process appear in Section VIII. Principal Investigator/Instructor Protocol Submissions, A. Protocol Cycle, 3. Period of protocol approval / expiration cycle.

Expired Protocols

If an approved protocol expires, the PI must stop work until a new protocol document set is submitted, reviewed and approved.

Review of forms other than Research Protocol Types

a) Teaching Lab protocol review

Teaching laboratories where potentially biohazardous materials are planned for use must apply for protocol and laboratory manual review as with research laboratory projects, using *Form D - Use of Biological Materials in Teaching Laboratories*.

Either the full IBC or a subcommittee of the IBC will review Teaching Lab Protocols. Protocol review follows the same process and timeline as research protocols. Pre-review and requests for clarification follow the same process. Laboratory facilities must pass biosafety inspection prior to the start of teaching using the BSL level materials proposed. Faculty in teaching laboratories are required to complete modification forms whenever there is a change in key personnel and the materials in use. The IBC Coordinator will provide Department chairs with the status of protocols for teaching labs in their divisions, while ensuring the Teaching Lab faculty receives the official letter or Approval, Deferred or Disapproval status.

b) Transgenic* plant field trials (rDNA)

The BSO and/or a subcommittee of the IBC will review all transgenic field trials. The BSO and/or subcommittee reports to the IBC, which reviews the information and votes to approve, defer, or disapprove these activities. Any committee member may call for additional review. The level of review is determined by the complexity of the proposed activity.

Planting of deregulated transgenic plants will be sufficiently reviewed by the BSO, while planting of transgenic plants to produce pharmaceuticals or industrial compounds may require a specialized subcommittee and/or in depth review by the full committee (in addition to the requirements found at XVI. f.).

*Transgenic plants are plants that have been genetically engineered, a breeding approach that uses recombinant DNA techniques to create plants with new characteristics. They are identified as a class of genetically modified organism (GMO).

C. Communication by or with the IBC

The primary communication for the IBC is through the Committee email box, biosafe@isu.edu. The IBC Compliance Coordinator monitors this email; answering or forwarding messages to the IBC Chair or members as needed. This is the account that distributes IBC questions to PIs, relays approval letters and notices. A message from this mailbox is likely to have some bearing on research or teaching laboratories and projects of faculty.

Members and other ISU personnel should "copy" this account when sending IBC or protocol related questions to other members.

PIs and Teaching Lab Faculty should use this account to turn in their protocol documents, or to

answer questions issued from the IBC or the Coordinator during protocol review.

biosafe@isu.edu is also an appropriate mailbox for the IBC Chair, and for matters for the attention of the IBC Compliance Coordinator. If email must be directed to an individual email account, please copy biosafe@isu.edu to ensure it does not get buried in a member's email.

Subject Line of emails

All persons – IBC members, ISU EH&S or Facilities staff or PIs/Teaching Lab Faculty are encouraged to use the subject line of their emails to direct their messages. Once a protocol has an ID assigned, please include this ID number in your subject line.

Appendix A – SOP 001 – Reporting Concerns

Institutional Biosafety Committee (IBC) Standard Operating Procedure
SOP 001
IBC Procedures for the Investigation and Reporting of Concerns Regarding Biological Materials Use

The purpose of this procedure is to establish guidelines for the investigation of concerns regarding the misuse of rDNA and potentially biohazardous materials or deficiencies related to their handling.

Definition: Allegations of misuse of rDNA and potentially biohazardous materials (and substances described in the ISU IBC Handbook) including the following:

- The wrongful or negligent handling of these materials, and
- Non-compliance with established procedures or policies.

A. Procedure

Notice of the misuse of potentially biohazardous materials may be reported to any of the following responsible parties: the Institutional Official (IO), Institutional Biosafety Committee (IBC) chair, the Biosafety Officer, the IBC Compliance Coordinator (IBC CC) or any IBC member, in person, on the phone, by email or written note. In addition, concerns can be submitted on-line through MySafeCampus.com. Reports submitted on-line are relayed to the Assistant Vice President for Research Outreach and Compliance who sends them to biosafe@isu.edu. Reports may be made anonymously and by anyone, ISU-affiliated or not.

1. Any of the IBC parties listed above, upon receiving a reported concern, will send them to biosafe@isu.edu no later than 3 calendar days after receipt. The IBC CC will send such messages to IBC Chair upon receipt. If the report concerns the Chair, the IO is notified instead.
2. Meeting is convened

During the academic year, the Chair convenes a meeting of the IBC within 5 working days of receiving a concerns report. Between May 15th and August 15th, the meeting will be convened within 10 working days. Summer meetings will not require a quorum to be present, with call-ins allowable.

During this meeting the IBC membership reviews and makes a determination:

a. To perform further investigation, or
b. To take no action.

This decision is based on a review of the report, referencing the IBC Handbook and relevant guidance. All decisions and actions by the IBC are then summarized in minutes of the meeting. If further investigation is determined to be required, either the

- IBC Chair and at least one other committee member will conduct the investigation, or
- If the Chair is involved in the report, the IO will select a subcommittee to conduct the investigation. In either instance, upon completion of the investigation, the investigating parties will report back to the full IBC.

It is important to avoid actual or perceived conflicts of interest in this process. IBC members who have a conflict of interest (related to the investigation) should declare that fact and recuse themselves from the investigation.

The IBC or IO should charge the appointed person(s) or subcommittee with its requirements for information gathering and impose a completion date. The assigned investigation completion date will be no later than 20 working days after the IBC decision to investigate.

Within 5 working days of the IBC deciding to conduct an investigation, the PI named in the allegation will be notified of the IBC investigation.

The nature of the information required for the investigation will vary depending on the circumstances, but often involves:

- interviewing complainants (if known); any persons against whom allegations were directed;
- pertinent program officials or unit directors;
- observing the biological laboratory conditions; and
- reviewing any pertinent records.

The designated investigator(s) written report to the IBC should summarize: the concern(s),

- the results of interviews,
- the biological laboratory conditions, and
- the results of records and other document reviews.

The report should also contain:

- any supporting documentation such as correspondence, reports, and process records,
- conclusions regarding the substance of the concerns *vis-à-vis* requirements of the applicable regulation or guide, and institutional policies and procedures, and

recommended actions, if appropriate.

B. Outcomes and Final Actions

Findings

Upon receipt and evaluation of the concerns report, the IBC may request further information or find that:

a. There was no evidence to support the concern or complaint, or

b. The concern or complaint was valid.

The IBC provides a findings report to the IO within 20 days with the results of the investigation.

If the complaint is determined to be valid, subsequent actions of the IBC are listed in the findings report.

These actions may include the following:

- Implementing measures to prevent recurrence (ex: changes in administrative, management or IBC policies and procedures, and may include sanctions);
- Notifying funding or regulatory agencies, as required; and
- Institutional sanctions as determined by the IO. These may include:
    - counseling;
    - issuing letters of reprimand;
    - mandating specific training aimed at preventing future incidents;
    - monitoring by the IBC or IBC-appointed individuals of the research project;
    - temporary revocation of privileges to conduct biosafety research pending compliance with specific, IBC-mandated conditions;
    - permanent revocation of privileges to conduct biosafety/biomaterials research; and
    - recommending to the IO that institutional (e.g., reassignment, termination of employment) sanctions be imposed.

A letter will be issued to the PI from the IO within 20 days of the IBC finding, outlining the results and any sanctions to be implemented. The PI will have 20 working days from date of the letter to refute the finding in writing, submitted to the biosafe@isu.edu email or in person to the IO. The IO will meet with the PI and the faculty ombudsperson and render a final decision within 20 working days from the date of the PI's letter of refutation.

A notice of final results will be issued to the complainant, any persons against whom allegations

were directed, and pertinent ISU officials (appropriate supervisors, the public affairs office, institutional attorneys, etc.) when all proceedings are complete.

Abbreviations

IO – Institutional Official
IBC – Institutional Biosafety Committee
IBC CC – IBC Compliance Coordinator
PI – Principal Investigator

Appendix B. Information for Completing Forms A – D.

A. Determine the project Risk Group (RG)

"Risk groups are the result of a classification of microbiological agents based on their association with, and resulting severity of, disease in humans. The risk group of an agent should be one factor considered in association with mode of transmission, procedural protocols, experience of staff…" Source: BMBL 5th Edition, Section III, Principles of Biosafety.

Table 1: Classification of Infectious Microorganisms by Risk Group

Risk Group Classification	NIH Guidelines for Research involving Recombinant DNA Molecules
Risk Group 1	Agents not associated with disease in healthy adult humans.
Risk Group 2	Agents associated with human disease that is rarely serious and for which preventative or therapeutic interventions are *often* available.
Risk Group 3	Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).
Risk Group 4	Agents 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).

Table Source: BMBL 5th Edition, Section II, Biological Risk Assessment

B. Determine Biosafety Levels

Both the NIH Guidelines (April 2019) and the CDC's BMBL, 5th Edition, describe four Biosafety Levels (BSLs). These biosafety levels consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and based on the potential hazards imposed by the agents used and for the laboratory function and activity. Biosafety Level 4 provides the most stringent containment conditions, Biosafety Level 1 is the least stringent. Biosafety Level 3 or 4 work is not allowed at ISU.

Biological safety or biosafety is defined as the development and implementation of administrative policies, work practices, facility design, and safety equipment to prevent transmission of biologic agents to workers, other persons, and the environment. Biosafety defines the containment conditions under which infectious agents can be safely manipulated. The objective of containment is to confine biohazards and to reduce the potential exposure of the laboratory worker, persons outside of the laboratory, and the environment to potentially infectious agents.

Containment can be accomplished through the following means:

Primary Barriers:

Protection of personnel and the immediate laboratory environment using good microbiological

technique (laboratory practice) and using appropriate safety equipment.

Secondary Barriers:

Protection of the environment external to the laboratory from exposure to infectious materials through a combination of facility design and operational practices.

A generalized summary of the different biosafety level requirements is shown in **Table 2, Biosafety Levels with Requirements.** Refer to the BMBL or NIH Guidelines for more detail (next page).

Table 2: Biosafety Levels with Requirements

Biosafety Level	**Description**
Biosafety Level 1 (BSL-1)	
Agents:	Not known to cause disease in healthy adult humans.
Practices:	Standard microbiological practices.
Safety Equipment: (Primary barriers)	None required.
Facilities: (Secondary barriers)	Open bench top with sink available.
Biosafety Level 2 (BSL-2)	
Agents:	Moderate risk agents that are present in the community and associated with human disease of mild to moderate severity.
Practices:	BSL-1 practice plus limited access, biohazard warning signs, "sharps" precautions, and a SOP defining any needed waste decontamination or medical surveillance policies.
Safety Equipment: (Primary barriers)	Primary barriers include a Class I or II Biological Safety Cabinet (BSC) or other physical containment devices used for the manipulation of agents that cause splashes or aerosols of infectious materials; Personal Protective Equipment (PPEs) including laboratory coats, gloves, face and eye protection as needed
Facilities: (Secondary barriers)	BSL-1 plus the availability of an autoclave for decontamination.
Biosafety Level 3 (BSL-3)	
Agents:	Indigenous or exotic agents with a potential for aerosol transmission; and which may cause serious or potentially lethal infection.
Practices:	BSL-2 practice plus controlled access, decontamination of all waste, and decontamination of lab clothing before laundering.
Safety Equipment: (Primary barriers)	Primary barriers include a Class II BSC or other physical containment device used for the manipulation of agents, PPE to include protective lab clothing, gloves, face and eye protection, and respiratory protection as needed.
Facilities: (Secondary barriers)	BSL-2 plus physical separation from access corridors, self-closing and double door access, exhausted air not recirculated with negative airflow into laboratory

Table Source: BMBL 5th Edition, Section II, Biological Risk Assessment (summarized)

Appendix C. Definitions

The following select terms are common to the consideration of potentially biohazardous materials and select agents. This is not an exhaustive list and other resources will be essential for protocols and biosafety laboratory manuals. They appear in order of importance, not alphabetically.

- Potentially Biohazardous Material: The Institutional Biosafety Committee reviews and approves many areas of biologically related research, teaching and outreach activities. The ISU IBC defines potentially biohazardous materials to include all of the categories below. Projects involving material(s) included in any of the following categories must be submitted for IBC approval.
    - Synthetic or recombinant nucleic acid molecules, including recombinant DNA
    - Genetically modified organisms including, but not limited to:
        a. Animals, plants, invertebrates, and/or other organisms created by ISU employees or in/on ISU property,
        b. Genetically modified whole plants (even those commercially available and not requiring APHIS permits; to include planting of USDA deregulated commercially available seed in the field)
        c. Transgenic field trials, any genetically modified organisms to be introduced into the environment (by ISU personnel and/or on ISU property),
        d. Field testing of plants engineered to produce pharmaceutical and industrial compounds,
- Any organisms requiring federal permits from APHIS, CDC, FDA, EPA, etc., such as:

Pathogens/infectious agents (human, animal, plant, and other),

Select/Biological Agents and Toxins (CDC and USDA),

Human and primate tissues, cells and cell lines, blood and blood products, and potentially infectious body fluids.

- Work with animals or vectors known or suspected to be reservoirs of RG2 or RG3 infectious agents when such work increases potential exposure risks to personnel or other animals,
- Oncogenic viruses used in conjunction with animals
- Nanotubes and nanoparticles

The IBC also serves as an advisory committee for University projects that involve possible biohazards that do not appear to fall into one of these areas. When it is unclear as to whether a material constitutes a potential biohazard, consult the IBC.

Direct questions to the Office for Research Outreach and Compliance, the IBC Compliance Coordinator, or ISU Biosafety Officer.

- Biosafety: Is the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials. The principals of biosafety are containment and risk assessment. Biosafety is achieved by implementing various degrees of laboratory control and containment, through laboratory design and access restrictions, personnel expertise and training, use of containment equipment, and safe methods of managing infectious materials in a laboratory setting.
- Biosecurity: Protection of high-consequence microbial agents and toxins, or critical relevant information, against theft or diversion by those who intend to pursue intentional misuse.
- Biologic Terrorism: Use of biologic agents or toxins (e.g., pathogenic organisms that affect humans, animals, or plants) for terrorist purposes.
- Blood: Human and primate blood, and blood components that include plasma or serum, platelets or other cells, wound exudates, and other products derived from this blood.
- Bloodborne pathogens: Pathogenic microorganisms present in human blood, which can cause disease in humans. Includes the hepatitis B virus (HBV), hepatitis C virus (HCV) and the human immunodeficiency virus (HIV).
- Chain of Custody: The serial holders of a pathogen, each of who is responsible for securing the pathogen and are accountable for its documentation.
- Contaminated: Presence or reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.
- Decontamination: Use of physical or chemical means to remove, inactivate or destroy bloodborne pathogens or other biohazardous agents on a surface or item to the point where they are no longer capable of transmitting infectious particles and the item or surface is rendered safe for handling, use, or disposal.
- Engineering Controls: Controls such as sharp disposal containers or self-sheathing needle that isolate or remove the hazard from the workplace.
- Genetic Engineering: Genetic engineering refers to the process in which genes or other genetic elements from one or more organisms are inserted into the genetic material of a second organism using molecular biology methods. Moving a new gene or genes in this way allows researchers to introduce new traits into an organism

from individuals of the same species or from unrelated species.

- Genetically Modified Organism (GMO): An organism whose genetic material has been altered using techniques generally known as recombinant DNA technology.
- HIV: Human immunodeficiency virus.
- Institutional Official (IO): The facility official who has been designated the responsibility and authority to ensure requirements for compliance with federal, state and local regulations are met.
- Other potentially infectious materials (OPIM): The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures; any body fluid that is visibly contaminated with blood and all body fluids where it is difficult or impossible to differentiate between body fluids; any unfixed tissue from human and HIV/ HBV containing culture medium.
- Parenteral: Entry into the body by other means than through the digestive tract, such as by piercing mucous membranes or the skin by needle sticks, human bites, cuts and abrasions.
- Personal protective equipment (PPE): Special clothing/equipment worn by a worker to protect against a hazard. General work clothes (uniforms, pants, shirts, blouses) not intended to function as protection against a hazard are not considered personal protective equipment.
- Regulated waste: Solid or liquid waste that may present a threat of infection to humans. Examples include:
    - Non-liquid or semi-liquid tissue and body parts from humans and other primates; laboratory and veterinary waste which contain disease-causing agents; discarded sharps; and blood, blood products and body parts from humans and other primates;
    - Other potentially infectious materials; contaminated items that would release blood;
    - Other potentially infectious materials in a liquid or semi-liquid state if compressed;
    - Items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; and
    - Contaminated sharps and pathological and microbiological wastes containing blood or other potentially infectious materials.
- Risk: A measure of the potential loss of a specific biologic agent of concern, on the basis of the probability of occurrence of an adversary event, effectiveness of

protection, and consequence of loss.

- Select Agent: Specifically regulated pathogens and toxins as defined in Title 42, CFR, Part 73, including pathogens and toxins regulated by both DHHS and USDA (i.e., overlapping agents or toxins) and plant pathogens regulated by USDA alone.
- Select Agent Access: The ability to take physical possession of select agents/toxins. Such access includes areas where unlocked freezers, small unsecured, yet locked, containers, and cabinets contain select agents/ toxins.
- Select Agent Area: An area where select agents/toxins are used or stored, regardless of whether they or not they are in locked containers. Such an area would be a laboratory room or connecting rooms where select agents are used or stored. Corridors outside the laboratory room where select agents are used or stored may or may not be declared a select agent area, depending upon the biosecurity plan approved by the IBC.
- Threat: The capability of an adversary, coupled with intentions, to undertake malevolent actions.
- Threat assessment: A judgment, based on available information, of the actual or potential threat of malevolent action.
- Vulnerability: An exploitable capability, security weakness, or deficiency at a facility. Exploitable capabilities or weaknesses are those inherent in the design or layout of the biologic laboratory and its protection, or those existing because of the failure to meet or maintain prescribed security standards when evaluated against defined threats.
- Vulnerability assessment: A systematic evaluation process in which qualitative and quantitative techniques are applied to determine an effectiveness level for a security system to protect biologic laboratories and operations from specifically defined acts that can oppose or harm a person's interest.

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