Idaho State University | Research Outreach and Compliance

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INSTITUTIONAL BIOSAFETY COMMITTEE 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.

OFFICE FOR RESEARCH

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https://www.isu.edu/research/research-integrity-and-compliance/biosafety/

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 reject 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 (including 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 safely 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 harm 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
- 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 Integrity 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 pRICedures being performed.

F. Principles that Govern the IBC (Primary Rules)

The IBC developed this handbook and operates based upon the following regulations and guidelines, listed below.

- 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 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

- Federal Permits

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:

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

- External University Protocols

When an ISU PI seeks to join a biosafety project at an institution of than ISU, the ISU IBC must be notified. Submit the other institution's IBC protocol and approval. If not included in the protocol, include a description of the specific activities planned for the ISU PI on the project, at the other institution.

An ISU IBC number and approval will not be issued for this sort of work, but the approval and PI activities will be kept on file.

If part of the project will be done at ISU, a full IBC protocol is needed for approval of that section of work.

- External Participants on ISU Projects

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 before the start of work.

II. Membership of the IBC

A. Number of Members

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

B. 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 Health and Safety office.

The IBC will include at least two voting members from the surrounding community of any ISU campus. Neither of these members will be affiliated with Idaho State University and both shall represent the interest of the surrounding community concerning 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 an 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's understanding of operational, laboratory, and waste considerations.

III. 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.

B. 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.
- Documented non-participation (refusing to vote when no conflict of interest exists), or non-attendance (more than two meetings per semester without cause).
- Non-disclosure of a known conflict of interest related to protocols reviewed by the IBC.

C. 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.
- For documented non-attendance (more than two meetings per semester without cause), or for non-participation (refusing to vote).
- Non-disclosure of a known conflict of interest related to protocols reviewed by the IBC.

D. Training of IBC Chair and Members

- Orientation

A new member orientation, including an introduction to the federal regulations, ISU IBC meeting procedures, the review process, and the IBC Handbook with forms, will be conducted by the Chair and/or IBC Coordinator. The Assistant Vice President for Research Integrity and Compliance (RIC) 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, online 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.

- 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.

- Conflict of Interest

No IBC member may participate in the IBC's initial or continuing review of any project in which the member has a conflicting interest, except to provide the 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.

- Compensation and Liability Coverage

IBC members are not compensated for their IBC participation.

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.

IV. Duties and Responsibilities

A. The Institutional Biosafety Committee

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 the 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 fulfill 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 regularly 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) 282-1232 or via biosafe@isu.edu.

B. IBC Chair

The Chair conducts all IBC meetings following 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 by all applicable federal, state, and institutional regulations, policies, and pRICedures. The Chair is the designated signatory for the IBC.

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

The IBC Chair will report in writing within 10 working days to the Vice President for Research, Department Chair and Dean, Agency Head (sponsor) or any applicable regulatory body, any occurrence of adverse events as mandated in the Federal Regulations. If applicable a report will be sent to the Funding Sponsor. 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 before the meetings in preparation for a vote on the specific protocol application. Additionally, the use of a shared web-hosted repository may be expected, unless an accommodation is required.

- Protocol Discussion

IBC members will actively participate in the 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 before 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, Modifications, or Renewals

The IBC reviews and votes to approve, give pending approval or reject all requested changes (modifications) to currently approved research or activities before their implementation by the PI.

The IBC also reviews and votes to approve, give pending approval or reject 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.

- IBC CC Responsibilities

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 a 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, pending approval, and rejected 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.

Maintains an Inpsection Report Record that lists the approve biosafety laboratories with review dates and results.

E. The ISU Biosafety Officer (BSO)

The BSO is a voting member.

- BSO Responsibilities

Reviews laboratory biosafety manuals and standard operating pRICedures (SOPs) for compliance with guidelines for BSL and ABSL pRICedures

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 pRICedures 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 helps faculty 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) per USDA/ARS 242.1M, Appendix 9A, *Project Team Roles and Responsibilities as They Relate to Biological Safety Issues.*

F. 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.

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 before commencing work with biological or potentially biohazardous materials for a project (Register the potentially biohazardous agents they propose to use with the IBC via a modification form or protocol registration form).

See the Principal Investigators IBC Protocol Handbook.

Perform risk assessments (and develop plans for all activities accordingly).

Ensure that all project personnel (including the PI) complete the applicable CITI training before 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 workers 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.

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

- Unit Leaders 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 before 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 pRICedures 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.

H. Laboratory Workers, Postdocs, Students, Individuals

Persons who work in the laboratory in a technical (rather than purely administrative) capacity are defined as laboratory workers, 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.

- Responsibilities

Conscientiously follow lab-specific biosafety practices and pRICedures.

Complete and maintain a current status of CITI Biosafety training as applicable to the 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, pRICedural discrepancies, spills, or accidental releases as soon as they occur.

Report to the Office for Research Integrity and Compliance any significant violations in biosafety policy, practices, or pRICedures 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 pRICedures to supervisors, the PI, the Office for Research Integrity and Compliance, or members of the Institutional Biosafety Committee.

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 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 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, Department Chair and Dean, Agency Head (sponsor) or any applicable regulatory body, any occurrence of adverse events as mandated in the Federal Regulations. If applicable a report will be sent to the Funding Sponsor. 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 pRICedures may be brought forward by any person and the IBC must recommend appropriate action.

In addition, concerns can be sent online through Maxient at the URL: https://cm.maxient.com/reportingform.php?IdahoStateUniv&layout_id=75 .

The Maxient 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. Meetings Schedules

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

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 first meeting of the year.

Among other business, September 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 the summer.

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 the executive session). Meeting dates for the current semester are published on the Research Integrity and Compliance Biosafety website.

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

Seven calendar days before a meeting the IBC CC will send notice to each committee member of the availability of the following (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 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. They 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 presentations 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 following determinations.

- 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".

- Pending Approval

The IBC may vote to request protocol changes and/or submission of additional information. In this instance, approval is pending for submission and evaluation of the requested changes, information, or other requirements by the IBC. This includes waiting for corrections or modifications required by the inspection(s) done to the lab/work space. The IBC CC will contact the PI requesting additional information or to list the specific requirements to be completed before the IBC approving.

If the IBC determines the information or requirements needed are minor, then once the additional information or requirements are met, reviewed, and accepted by the 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 before approving.

The IBC will maintain pending approval 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.

- Rejected

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 reject the protocol.

D. Modifications to Approved Protocols

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

- 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 the addition of a new class of bio-hazardous material not previously utilized, the addition of materials requiring a higher biosafety level, or the addition of materials or procedures that may increase the project's associated risks. The change of the PI is also considered a significant change. Some changes may be so significant that a new protocol is required. For questions about this please contact the IBC Chair.

- 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 the 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 another member review.

E. 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, pending approval, or rejected.

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.

F. 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 under 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 or BSO may issue suspension notice.

The BSO has the authority to suspend a protocol in the instance where a serious issue of safety or regulatory compliance is apparent. These safety and regulatory compliances are defined by Chapter I. "Authority and Purpose", section F. "Principles that Govern the IBC (Primary Rules)" of this handbook and Occupational Safety and Health Administration (OSHA). For the BSO to suspend work, there must be a clear and imminent threat to persons and/or property. The BSO may suspend work if there have been several documented warnings that have gone unaddressed.

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.

G. 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, pending approval due to IBC request for changes or new information, or rejection. For pending approval protocols, all requirements that must be met for the committee to approve are detailed.

H. Voting Requirements

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

Full voting rights of all reviewing members

Each member has one vote.

No absentee votes are allowed.

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.

I. 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 PRICedures and Guidelines

Written IBC pRICedures 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 at (208) 282-1232, (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 Records

All protocols reviewed and related materials will remain on file in the Office for Research Integrity and Compliance (RIC) for three years after the 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 RIC as a record of the committee's activities. Policy guidance and forms will be disseminated from and stored by RIC 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/RIC website. Any questions regarding the IBC review or the content of

this handbook should be directed to the IBC Chair via (208) 282-1232 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 the 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 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 before shipping. Address questions to the Assistant Vice President for Research Integrity and Compliance who is ISU's Export Control Officer.

IX. Appendix A. SOP-001 Reporting Concerns

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

The purpose of this pRICedure 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 pRICedures or policies.

A. PRICedure

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 online through Convercent (formally MySafeCampus.com) at the URL: https://app.convercent.com/en-US/LandingPage/76cab852-d82d-ec11-a985-000d3ab9f062.

Reports submitted online are relayed to the Assistant Vice President for Research Integrity 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 September 1st, the meeting will be convened within 10 working days. Summer meetings will not be required to be in person, with call-ins allowable.

During this meeting the IBC membership reviews and decides:

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 the 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 investigate, 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

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.

B. The concern or complaint was valid.

The IBC provides a finding 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 pRICedures, 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 Provost 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 the 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 pRICeedings are complete.

C. Abbreviations

IO – Institutional Official

IBC – Institutional Biosafety Committee

IBC CC – IBC Compliance Coordinator

PI – Principal Investigator

X. Appendix B. Information for Completing forms A-D

A. Determine the Project Risk Group (RG)

"The Risk Group (RG) of an agent is an important factor to be considered during the biosafety risk assessment process. Biological agents and toxins are assigned to their relevant Risk Groups based on their ability to cause disease in healthy human adults and spread within the community." Source: BMBL 6th Edition, Section III, Principles of Biosafety

Table 1: Classification of Infectious Microorganisms by Risk Group

Risk Group Classification	Basis for the Classification of Biohazardous Agents by Risk Group (RG)
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: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid, Appendix B – Table 1.

B. Determine Biosafety Levels

Both the NIH Guidelines (April 2019) and the CDC's BMBL, 6th 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 biological 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 a 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.

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. Eye wash station 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 6th Edition, Section II, Biological Risk Assessment (summarized)

XI. 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.

A. 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 include, but are not limited to:

- Animals, plants, invertebrates, and/or other organisms created by ISU employees or in/on ISU property,
- Genetically modified whole plants (even those commercially available and not requiring APHIS permits; to include the planting of USDA deregulated commercially available seed in the field)
- Transgenic field trials, any genetically modified organisms to be introduced into the environment (by ISU personnel and/or on ISU property),
- 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

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 material constitutes a potential biohazard, consult the IBC. Direct questions to the

Office for Research Integrity 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 principles 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 is 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 sharps disposal containers or self-sheathing needles 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 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 pRICedures; 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, based on the probability of occurrence of an adversary event, the 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 containing 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.