The ISU Institutional Biosafety Committee (IBC) Manual

Division for Research Integrity

and

Institutional Biosafety Committee

Idaho State University

1651 Alvin Ricken Drive

Pocatello, ID 83201

208-282-2179
TABLE OF CONTENTS

I. Introduction .................................................................................................. 5

II. Institutional authority under which the IBC is established ................. 6

III. Purpose of the IBC...................................................................................... 6

IV. Research and other activities requiring IBC review and approval ....... 6

V. Principles which govern the IBC............................................................... 8

VI. Duties and responsibilities ....................................................................... 9
    a. Principal investigators and laboratory supervisors ......................... 9
    b. Laboratory workers, postdocs, students, and other individuals ....... 9
    c. Unit Heads (Deans, Chairs, and Directors) ..................................... 10
    d. Institutional Biosafety Committee (IBC) ......................................... 10
    e. ISU Biosafety Officer (BSO) ......................................................... 11
    f. ISU Technical Safety Office ......................................................... 12

VII. Authority of the IBC .................................................................................. 12
    a. Scope of authority defined ............................................................. 12
    b. Authority to approve, modify, or disapprove studies .................... 12
    c. Authority to require progress reports from investigators
       and oversee the conduct of the study ........................................... 13
    d. Authority to approve or disapprove amendments .......................... 13
    e. Authority to suspend or terminate approval of a study ................. 13

VIII. Membership of the IBC .......................................................................... 14
    a. Number of members ...................................................................... 14
    b. Qualification of members ............................................................... 14
    c. Diversity of members .................................................................... 14

IX. Management of the IBC ............................................................................. 15
    a. Chair ............................................................................................. 15
       • Selection and appointment ......................................................... 15
       • Duties ....................................................................................... 15
       • Removal ................................................................................. 15
    b. IBC members .................................................................................. 15
       • Selection and appointment ......................................................... 15
       • Duties ....................................................................................... 15
       • Removal ................................................................................. 15
    c. Training of IBC Chair and members ............................................. 16
       • Orientation .............................................................................. 16
       • Continuing education ............................................................. 16
       • Reference material ............................................................... 16
d. Liability coverage for IBC members ...........................................................16

e. Use of consultants ......................................................................................17

f. Secretarial and administrative support staff ...............................................17

X. Conflict of Interest policy ............................................................................17

a. Financial conflict of interest ........................................................................17

b. Non-Financial conflict of interest ................................................................18

- No selection of IBC members by investigators ........................................... 18
- Prohibition of investigator participation in IBC deliberations and voting on proposals ........................................................... 18

XI. Functions of the IBC ..................................................................................... 18

a. Conducting initial and continuing reviews .................................................. 18

b. Reporting findings and actions of the IBC to the investigator ................. 18

c. Determining which studies require review more often than annually ...... 18

d. Reviewing and approving changes or amendments.............................. 19

e. Ensuring that changes in approved research are not initiated without IBC review and approval except where necessary to eliminate apparent and immediate hazards ................................................. 19

f. Ensuring prompt reporting to the IBC of unanticipated problems involving risks to subjects or others ........................................................... 19

XII. Operations of the IBC .......................................................................................20

a. Scheduling of meetings .............................................................................20

b. Pre-meeting distribution of IBC review materials to members ...............20

c. The review process ....................................................................................20

- Description of the review process .............................................................. 20
- Review Levels ............................................................................................. 20
- Subcommittee review .............................................................................. 21

d. Voting requirements ...................................................................................22

- Quorum required ....................................................................................... 22
- Full voting rights of all reviewing members ................................................ 22
- No proxy votes .......................................................................................... 22
- Prohibition of conflict-of-interest voting .................................................... 22

e. Communication from IBC to investigator conveying IBC decisions ........23

f. Appeal of IBC decisions: criteria for appeal .............................................. 23

XIII. IBC record requirements ...............................................................................23

a. IBC membership roster .............................................................................23

b. Written procedures and guidelines ............................................................23

c. Minutes of meetings ...................................................................................23

d. Retention of records ..................................................................................24

e. Communication to and from the IBC ........................................................ 25

XIV. Information the investigator provides to the IBC ...........................................25

a. Biosafety Approval Form (BAF) .................................................................25

b. Deregulated Field Planting Registration Form (DFPRF) ...........................25

c. Teaching activities ......................................................................................25

d. Requests for modification in study after initiation ..................................... 25

e. Reports of unexpected or adverse events .................................................. 26

f. Three year renewal and project expiration ................................................ 26

g. Student research ....................................................................................... 26
XV. Biosafety laboratories (inspection, manuals, SOPs) ........................................... 27
   a. Biosafety laboratory inspection and review ..................................................... 27
   b. Biosafety manuals .......................................................................................... 27
   c. State of Idaho Bloodborne Pathogen Standard (ECP) .................................... 27
   d. Teaching activities ......................................................................................... 27

XVI. Materials and activities requiring additional permits or approvals .............. 27
   a. APHIS permits .............................................................................................. 27
   b. CDC permits ................................................................................................ 28
   c. FDA permits ................................................................................................ 28
   d. EPA permits ................................................................................................ 28
   e. American Type Culture Collection ................................................................ 28
   f. Field trials of genetically modified organisms .............................................. 28

XVII. Bloodborne pathogens .................................................................................... 28
   a. Idaho BBP Standard ...................................................................................... 28
   b. Bloodborne pathogens program and training ............................................... 29
   c. Biosafety level ............................................................................................... 29
   d. 29
   e. Human cell lines ........................................................................................... 29
      • Primary ........................................................................................................ 29
      • Established ................................................................................................. 29

XVIII. Biosecurity .................................................................................................... 30

XIX. Definitions ...................................................................................................... 31
I. Introduction

The Idaho State University (ISU) Institutional Biosafety Committee (IBC) is established under the authority of the Vice President for Research and is charged with providing a safe working environment for ISU faculty, staff, students, and visitors to campus. The IBC has the authority and obligation to stop any activity that the committee believes to be unsafe. The ISU Institutional Biosafety Committee Manual is the reference document detailing the policies and regulations governing research with biological materials and the requirements for submitting research proposals for review by the ISU IBC. The information contained in this handbook provides the groundwork for specific safety protocols adopted by the ISU IBC and is based on federal, state, county, and University regulations and guidelines.

Sections of the manual describe and explain the various aspects of the IBC protocol review process and regulatory requirements. Investigators should familiarize themselves with the contents of this handbook and carefully review sections of the manual that address their specific research activities before submitting proposals to the IBC.

The IBC operates within federal guidelines with respect to the review and approval of research protocols involving biological materials. The IBC reviews and approves many areas of related activities that may include: research, teaching, diagnostic, and extension activities utilizing recombinant DNA (rDNA) and/or potentially biohazardous materials and performed by faculty, students, visitors (including non-ISU employees working in ISU facilities), or employees of ISU. These requirements apply to all activities in or on ISU properties or facilities (owned, leased, or rented) and apply in equal measure to all ISU designated or sponsored activities. The IBC is comprised of faculty representatives from various academic disciplines at ISU, researchers, non-scientific members, representatives from University departments, and community representatives who are not affiliated with the University.

The University, investigators, their research staff, and the IBC share the collective responsibility for the safe and ethical conduct of research including all personnel, facilities, and equipment.

This collaboration must exist in a culture of trust, transparency, and honesty by upholding the highest ethical principles in the conduct of research and building public support for the pursuit of greater knowledge in a safe research environment.

The University Biosafety program is a team effort involving the Principal Investigator (PI), ISU Biosafety Officer, laboratory research and support staff, teaching staff, Institutional Biosafety Committee members, the Technical Safety Office, University Risk Manager, and the Animal Care and Use (IACUC), Human Subjects, and Radiation Safety Committees. The Biosafety program is inextricably linked to all other aspects of laboratory safety. This handbook has been structured to reflect this approach.

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. It is the responsibility of each PI to become thoroughly familiar with the contents of this manual, to make sure that his or her workers are compliant with the lab-specific Biosafety Manual, and to ensure that all work with potentially biohazardous materials is conducted in a safe and ethically sound manner, in accordance with ISU Safety Policies and Procedures (SPP), laboratory specific Biosafety manuals and Standard Operating
Procedures (SOP) detailed in the Biosafety Approval forms (BAF) for proposal submission.

It is essential that staff and students seek additional advice and training when dealing with potentially biohazardous agents to ensure the safety of employees, students, and the surrounding community. To assist in this goal, the services and resources of the ISU Biosafety Officer (BSO) and the staff of the Technical Safety Office (TSO) are available.

II. The institutional authority under which the IBC is established

The Idaho State University Institutional Biosafety Committee (IBC) is established under the authority of the Vice President of Research who serves as the Institutional Official (IO) for the IBC.

III. 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 (see section IV for complete list of these materials) and to assure compliance with current regulations and guidelines. PIs and/or laboratory supervisors at Idaho State University who either store such material or carry out research or diagnostic activities involving potentially biohazardous materials must submit the appropriate Biosafety Approval Form (BAF) to the Institutional Biosafety Committee prior to initiation of such activity. For field planting of deregulated items the Deregulated Field Planting Registration Form (DFPRF) must be submitted to the IBC.

It is the policy 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. All activities must be planned and executed in such a manner that projects conducted by one faculty member will not have an adverse effect on adjacent projects conducted by other scientists. The ISU IBC maintains all related records for 3 years after the completion of the activity.

Further, it is University policy that Risk Group (RG) 4 Agents (those that require facilities meeting the criteria of Biosafety Level 4) may not be used or stored at ISU. See the NIH Guidelines and CDC BMBL for a list of these agents. You may also reference the on-line reference provided by ABSA @ www.absa.com for assistance in determining appropriate agent risk groups.

IV. Research and activities requiring review and approval from the IBC

The IBC reviews and approves many areas of biologically related activities that include research, teaching, diagnostic, and extension activities. The ISU IBC defines potentially biohazardous materials to include all infectious organisms (bacteria, chlamydiae, fungi, parasites, prions, rickettsias, and viruses), select agents, and toxins that may cause disease in humans, animals, or plants, or may cause significant environmental or agricultural impact. Work with materials that may harbor infectious organisms, such as human or primate tissues, fluids, cells, or cell cultures are provided oversight through the ISU Bloodborne Pathogen Program. Additional oversight from the IBC is provided for cell cultures and tissues of human and non-human primate origin that contain characterized agents at Risk Group 2 (RG 2) or above.
The phrase "potentially biohazardous material" is used throughout this manual to indicate all biological materials that the IBC oversees. The list includes materials that are not included in the NIH Guidelines and materials that may not traditionally be considered biohazardous. Potentially biohazardous materials include (but are not limited to) each of the categories below. Projects involving material(s) included in any of these categories must be submitted for IBC approval using the appropriate BAF.

- Recombinant DNA (rDNA) or Synthetic Nucleic Acids (Form A).
- Pathogens/infectious agents (human, animal, plant, and other) (Form B).
- Select Biological Agents and Toxins (CDC and USDA) (Form B). Please note that possession, use, or transfer of Select Biological Agents and Toxins entails additional requirements – contact the Division for Research Integrity for additional information; 208-282-2179; www.isu.edu/research/integrity/bio.shtml.
  - Human and non-human primate blood, cells and cells lines, tissues or fluids that with potential for infection by RG2 or above organisms, or other potentially biohazardous material (Form C).

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, the IBC should be consulted. Questions should be directed to the Division for Research Integrity, or the ISU Biosafety Officer.

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. Thus the PI or supervisor should contact the IBC regarding the approval procedure for projects not covered by Forms A-C above, but for which IBC approval is required. Examples of such areas of research or activity are given below:

- Genetically modified organisms. Including, but not limited to:
  - Animals, plants, invertebrates, and/or other organisms created by ISU employees or used on ISU property.
  - Transgenic field trials, any genetically modified organisms to be introduced into the environment, including planting of deregulated items in the field (by ISU personnel and/or on ISU property),
  - Field testing of plants engineered to produce pharmaceutical and industrial compounds,
  - Any organisms, or agents requiring federal permits (including but not limited to): APHIS, CDC, EPA, FDA.
  - 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. Work with RG1 may be considered "exempt" but these activities must also follow protocol submission to the IBC for approval.
V. Principles which govern the IBC

No work should be considered so important that it jeopardizes the safety of the worker or the environment. The planning and implementation of specific 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 potentially biohazardous agents including recombinant DNA requires the use of precautionary measures dependent on the agents involved and the procedures being performed. It is the purpose of this manual to provide background information and guidelines to be used in conjunction with other resources for the evaluation, containment and control of potentially biohazardous materials in laboratories.

All non-exempt select agent work being performed under one of ISU protocols at another institution will require an assurance that the work is being performed in an approved select agent lab and that the user is an authorized, registered user. This written assurance from the other institution’s IO is required before the ISU IBC can approve this work. Alternatively, the project may be submitted for approval to the IBC at ISU.

The IBC developed this manual and operates based upon the following regulations/guidelines. URLs for these sites are given:

  

- 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).
  


- 42 CFR Part 73, Possession, Use, and Transfer of Select Agents and Toxins.

  

- USDA/ARS Facilities Design Standards, Chapter 9. Biohazard Containment Design
  
  [http://www.afm.ars.usda.gov/ppweb/242-01m.htm#H304](http://www.afm.ars.usda.gov/ppweb/242-01m.htm#H304)

VI. Duties and Responsibilities

a. Principal investigators and laboratory supervisors

The PI is primarily responsible for the people and activities in their laboratories. They are responsible to:

- Register the potentially biohazardous agents they propose to use with the IBC (via the appropriate BAF) prior to the commencement of any activities involving the use of these materials.

- Implement an appropriate biological safety program specific for their projects that includes a current Biosafety Manual (BSL-1 and/or BSL-2) for the individuals and activities under their purview. Lab specific manuals should reference appropriate sections of the ISU IBC manual.

- Evaluate all laboratory operations.

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

- Establish the appropriate biological safety containment levels in consultation with the ISU Biosafety Officer and ensuring adherence to these levels.

- Ensure strict adherence 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. A description of this training is a requisite component of protocols submitted via each BAF to the IBC for approval.

b. Laboratory workers, postdocs, students, and other individuals

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 the supervisor and PI.

Each individual in the laboratory who functions in a technical (rather than purely administrative) capacity is 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. Each individual must look out for her/his own
safety and that of their co-workers to ensure a safe working environment. It is the laboratory worker’s responsibility to:

- Conscientiously follow lab-specific biosafety practices and procedures as outlined in the laboratory Biosafety Manual.

- 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 immediately.

- Report to the Division for Research Integrity any significant violations in Biosafety policy, practices, or procedures that are not adequately resolved by the PI.

- Refuse to take any adverse action against any person for reporting real or perceived problems or violations of procedures.

- **Chairs and Directors have the following responsibilities:**

  - Require that prior to initiation of research, each investigator or laboratory director using potentially biohazardous material, completes and submits the IBC BAF.

  - Require that students receive instruction in safety procedures in teaching laboratories or in field work where the potential for exposure to a potentially biohazardous agent or material exists.

  - Determine that appropriate facilities and safety equipment are available for proposed research or instruction involving potentially biohazardous agents.

  - Provide leadership and support in laboratory safety at the management level in the unit.

Toward that end, the IBC will prepare an annual report on biosafety-related research that will be sent to the VPR. The VPR will provide this report to the chairs and deans. The document will include a signature page for chairs to indicate that they have received, read and approved the report. This form will be returned to the secretary of the IBC.

- **The Institutional Biosafety Committee (IBC)**

  The IBC is responsible for reviewing and approving practices and protocols for the handling of recombinant DNA and potentially biohazardous materials at all research facilities under the auspices of Idaho State University. The IBC also assists the TSO in the development and review of policy (i.e. SPPMs) involving potentially biohazardous agents. The IBC is comprised of faculty representatives from various academic disciplines and urban campuses at ISU, researchers, non-scientific members, and community representatives.
who are 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 with the appropriate BAF.

The Institutional Biosafety Committee can be reached by contacting the Division for Research Integrity, at (208) 282-2179.

- **The ISU Biosafety Officer (BSO)**
  
  The BSO is responsible for developing, leading, directing, and managing a comprehensive biological safety program for Idaho State University. The biological safety program must meet NIH, CDC, USDA, OSHA or and granting agency, Federal, State and local requirements. The program includes close cooperation and interaction with faculty committees approving research protocols and procedures; these include Use of Human Subjects, Institutional Animal Care and Use, Biohazards and Biosafety, Radioactive Materials and Radiation Devices. The BSO will provide guidance and consultation to assess the risk of working with potentially biohazardous materials (see section IV for a complete list). The BSO interacts with the ISU research, teaching, diagnostic, and extension communities to inform and ensure compliance with state and federal reporting or audit requirements, and effect actions to inspect and correct deficiencies when noted.

- The BSO coordinates and approves facility reviews. Facilities for activities at Biosafety Level -1 and -2 are reviewed initially and at 3 year intervals by the BSO. Biosafety Level-3 facilities are reviewed initially and annually thereafter by the BSO.

  Biosafety level 3 facilities must be commissioned by a team including:

  - The Biosafety Officer
  - The Chair of the Biosafety Committee
  - The University Architect
  - The University Mechanical Engineer
  - An independent third party consultant(s) with expertise in this subject matter.

- Reviews (initial and at regular intervals) the physical facilities and containment equipment for compliance with general CDC guidelines for Biosafety Level (BSL) and Animal Biosafety Level (ABSL) laboratories for research and diagnostic work in accordance with laboratory inspection checklists developed in coordination with the IBC.

- Coordinates with Facilities Operations for corrections, modifications and repairs to physical facilities.
• Reviews laboratory biosafety manuals and standard operating procedures (SOPs) for compliance with guidelines for BSL and ABSL procedures.

• Provides general guidance about health and safety standards, and assists the IBC in reviewing research proposals.

• Per SPPM S80.12, S80.13, S80.14, helps ensure that biohazard, sharps and glass wastes are properly transported out of laboratory buildings and are treated and disposed of properly after leaving these buildings per applicable state and federal regulations.

• Maintains list of approved laboratories at their specific Biosafety Level with review dates and results. The IBC requires BSO inspection of BSL-2 facilities at least once every three years and annual inspection of BSL-3 facilities.

• Assists PIs in the development of appropriate Biosafety Manuals for all activities using potentially biohazardous materials. Biosafety Manual Templates can be found at www.isu.edu/research/integrity/bio.shtml

• The ISU Technical Safety Office (TSO)
  The ISU TSO department supports research and other activities involving biological materials in areas of laboratory biosafety, public health, and occupational health and safety.

• Maintains programs and educational materials pertaining to laboratory safety.

• Implements the bloodborne pathogen standard medical surveillance program.

VII. Authority of the IBC

a. Scope of authority defined

The ISU IBC has the authority to approve, require modifications of, or disapprove all research, teaching, diagnostic, or extension activities (whether funded or non-funded) that fall within its jurisdiction as specified by both the federal regulations and Institutional policy.

b. Authority to approve, modify, or disapprove studies based upon consideration of biological safety aspects

The ISU IBC approves protocols for up to three years. After three years the protocol (BAF) must be resubmitted. Research that has been reviewed and approved by the ISU IBC may be subject to further review by federal or state agencies or by the IBC with any modification to the original protocol (Form C).

ISU officials may not approve research activities independently of the
Specifically, the ISU IBC functions autonomously from other committees and makes independent determination whether to approve or disapprove each protocol submitted, based solely upon whether or not biological safety aspects adhere to relevant regulations, guidelines, and policies. The ISU IBC has jurisdiction over all research involving regulated or potentially hazardous biological materials, thereby providing broader protection than required by federal or state regulations.

c. Authority to require progress reports from investigators and oversee the conduct of the study

Any approved research or protocol is subject to continuing IBC review and is generally re-evaluated at least every three years (or more frequently, if specified by the IBC).

d. Authority to approve / disapprove amendments

All modifications to currently approved research/activities are required to have IBC review and approval prior to implementation. Modifications are submitted on an Amendment Form D, subject to review by the IBC.

An amendment may require full IBC review if the modification is significant. Examples of significant amendments may include: the addition of potentially bio-hazardous materials that require a higher biosafety level, or the addition of materials or procedures that may increase the risks of the research. Administrative amendments may be approved by a sub-committee of the IBC that includes the IBC Chair and BSO. Examples of administrative amendments may include the addition of very similar potentially bio-hazardous materials to an approved protocol (if used under the same conditions as specified in that approval), change of laboratory room (if change is to an equivalent and approved facility), addition of personnel on the protocol, and change of PI or contact information.

The IBC modification approval is only valid until the end of the original approval period. For example, if the BAF original approval is issued on January 1, 2013 it will have an expiration date of December 31, 2015. If a modification is approved during this time, the approval still lasts only until December 31, 2015.

e. Authority to suspend or terminate approval of a study

The ISU IBC has the authority to suspend or terminate approval of research that is not being conducted in accordance with IBC requirements or that has been associated with unexpected serious consequences. Any suspension or termination of approval shall include a statement of the reasons for the action of the IBC, and shall be reported promptly to both the PI and unit head. Suspension of any protocol requires a majority vote of the full committee of the IBC.

Information concerning noncompliance or perceived noncompliance
VIII. Membership of the IBC

a. Number of members

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

b. Qualification 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.

c. Diversity of members

- The IBC will be sufficiently qualified through the experience, expertise, and diversity of the members, to promote respect for its advice and capability to assess the safety of research, teaching, diagnostic, and extension activities and to identify any potential risk to workers, public health, or the environment. Current committee members will assist the IO in assuring the diversity of members.

- The IBC will include at least two 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.

- The BSO will be a voting member.

- As appropriate at least one member whose primary expertise is in plants, plant pathogens, and plant pest containment principles and one member with expertise in animals and animal containment principles will be appointed to the IBC Committee.

- Every effort will be made to ensure that at least two of the following fields of expertise will be represented on the IBC: pharmaceutical science, immunology, and animal research.

- Every effort will be made to include a voting member from the IACUC.

- Every effort will be made to include a non-voting member from Facilities Operations (FacOps).

- Every effort will be made to include representation on the IBC from
IX. Management of the IBC

a. The Chair

Selection and appointment

The Chair is appointed by the Vice President for Research and based upon the recommendation of the IBC. The Chair serves as chair for at least one year and may be reappointed. The Chair is also a voting member.

If the Chair is unavailable for a scheduled meeting any member may be asked by the Chair to act as a substitute. If a Chair is unavailable for a period of time exceeding 3 months the Institutional Official may appoint a temporary Chair.

Duties

The Chair directs IBC meetings in accordance with institutional and federal requirements. She or he works closely with IBC members, the IO, the Research Integrity Officer, the IBC Secretary, the BSO, TSO, and investigators to ensure that research and other activities involving regulated or potentially bio-hazardous 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 and conducts all IBC meetings. The Chair may delegate signatory duties to Division for Research Integrity personnel.

Removal

The Chair may be removed or replaced by the IO after discussion with a quorum of IBC committee members and with a majority vote for dismissal.

b. The IBC members

Selection and appointment

Members are appointed by VPR, based upon the recommendation of the chair and other current committee members. ISU faculty members appointed to the IBC will serve on the board for a three-year term. Community and/or non-affiliated IBC members will also be appointed to the board for three-year terms.

Appointments to the committee typically begin August 16th of the year appointed and end August 15th three years later. At the conclusion of their terms a committee member may be appointed to an additional term and/or year(s) of service. There is no limit to the number of terms a member may serve on the IBC.

Duties
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.

Removal

IBC members may be removed or replaced by the IO after advisement from a quorum of other IBC members resulting in a majority vote for suggestion for removal and replacement.

c. Training of IBC Chair and members

Orientation

When a new member or chair is appointed to the IBC, the BSO and Chair of the IBC (when he/she is not a new member) will hold a New Member Orientation. This orientation will introduce new members to the federal regulations, ISU IBC meeting procedures, review process, and the IBC Manual laboratory specific and BAF forms.

Continuing Education

Continuing education of the IBC member is done through special training meetings as well as educational information distributed to members through newsletters or by discussing them at a full committee meeting. At a minimum this training will occur once a year. The IBC Secretary, BSO, and Research Integrity Officer may attend professional development conferences throughout the year to keep current on IBC issues.

Reference Materials

Each IBC member is provided with the URL of the ISU IBC Manual that includes the specific ISU IBC Policies and Procedures, and the list of BAF including lab specific biosafety manuals.

d. Liability coverage for IBC members

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.

e. 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 may be unaffiliated with ISU. The
f. Administrative support staff

The ISU IBC has an IBC Secretary to coordinate the privileged and confidential institutional review and approval process of proposed research activities involving biological materials.

The IBC Secretary

- Presents evaluations, recommendations, historical information and precedents regarding compliance with laws, regulations, and ethical and safety standards;
- Communicates committee requests to investigators for additional information and revisions and review responses;
- Prepares correspondence, reports, agendas, minutes, and certifications of review for funding agencies related to review and approval process;
- Maintains all records related to IBC activities.

X. Conflict of Interest policy

a. Financial Conflict of Interest

Investigators (or other project personnel) involved in a research project or other activity involving potentially biohazardous materials must disclose a potential financial conflict of interest within the BAF. In all cases, good judgment, openness of process and reliance upon objective, third party oversight can effectively safeguard the integrity of the research. Toward that end, the Conflict of Interest Committee will review the financial disclosure, and consider the potential conflict of interest (as outlined in ISUPP, #7070, ISU Policy and Procedures for Conflict of Interest in Sponsored Programs).

In the event that the Conflict of Interest Committee determines that an investigator has a potential conflict of interest that cannot be eliminated, and must be reduced or managed in some way, the IBC will carefully consider the specific mechanisms proposed to minimize the potential adverse consequences of the conflict prior to any decision to approve or disapprove the proposal in question.

b. Non-Financial Conflict of Interest

No selection of IBC members by investigators

The PI cannot select or recommend which IBC member(s) will review their protocol. Additionally, any IBC member must recuse himself or herself from review of their own proposal or if there exists any real or apparent conflict of interest in other proposals.
Prohibition of participation in IBC deliberations and voting by investigators

Reviews of applications will be conducted with objectivity and in a manner to ensure the exercise of independent judgment of each member. Members may not participate in a vote by the IBC on actions concerning projects or activities in which they have either an active role, or conflict of interest. Failure to abide by these provisions may be cause for removal of a member from the IBC.

As stated above, IBC members may 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. The IBC member must make any conflict of interest known to the IBC Chair. The member may provide to the IBC, if requested, additional information regarding the circumstances of a potential conflict of interest. A protocol submitted by another investigator from an IBC member's Unit or Section does not, in and of itself, constitute a conflict of interest.

XI. Functions of the IBC

a. Conducting initial and continuing reviews

The ISU IBC is responsible for the review and approval of all projects (whether funded or not funded) involving regulated or potentially biohazardous materials conducted under the auspices of Idaho State University regardless of funding source.

b. Reporting findings and actions of the IBC to the investigator

The IBC Secretary or BSO will report findings and actions of the IBC to the investigator. A letter signed by the Chair of the IBC will be sent following full committee vote to approve a protocol.

c. Determining which studies require review more often than every three years

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 or notification to the IBC.

d. Reviewing and approving changes/amendments to research activities

All modifications to currently approved research/activities are required to have IBC review and approval prior to implementation. Modifications are submitted on BAF Amendment Form D.
The IBC modification approval is only valid until the end of the original approval period. For example, if the BAF original approval is issued on January 1, 2013 it will have an expiration date of December 31, 2015. If a modification is approved during this time, the approval still lasts only until December 31, 2015.

e. Ensuring that changes in approved research are not initiated without IBC review and approval except where necessary to eliminate apparent immediate hazards

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 are encouraged to contact the IBC if this type of situation arises prior to implementation of the protocol change. Investigators are required to notify the Division for Research Integrity in writing of the change, within 72 hours, and include a written description of the change and events that necessitate immediate implementation.

For situations in which there is request for project initiation well in advance of the next full IBC meeting, PIs may request for initiation of the project. In these cases proposals will be reviewed by a sub-committee of the IBC and project initiation may be approved, with recommendations for full compliance. In such cases the proposal must be submitted for review by the full IBC and must have approval at that time. As for other proposals, a negative decision by the IBC will result in termination of the project. Pre-proposal initiation approval may not be followed by delayed proposal submission past the next IBC meeting; failure to submit a proposal, or a committee decision to defer, will result in project cessation until all concerns have been met, and with full committee approval.

f. Ensuring prompt reporting to the IBC of unanticipated problems

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

XII. Operations of the IBC

a. Scheduling of meetings

The full IBC will convene monthly throughout the academic year, unless
there is no business to be conducted, in which case a meeting will not be held.

Monthly meetings will be arranged by the IBC Secretary with an agenda sent by electronic mail. IBC meetings are open to the public and meeting dates for the current semester are published on the Division for Research Integrity’s website.

b. Pre-meeting distribution of IBC review materials to members

Seven calendar days prior to full meetings of the IBC at which voting is expected, the Secretary will send to each committee member:

1. Meeting agenda
2. Minutes from the previous meeting
3. All new protocols to be reviewed
4. Modification requests
5. Renewal requests
6. Continuing education materials

c. The review process

Description 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 source (or lack of a funding source). The IBC will consider all information presented with the BAF. The IBC may request additional information and/or clarification from the researcher.

Review

Upon receipt of a protocol, the IBC Secretary will pre-review the protocol for required signatures and completion. The Secretary will contact the investigator via phone or email if any additional materials are required.

Committee Review

The secretary will send protocols and any clarifying information to the full IBC committee at least 7 working days before the meeting.

The IBC will review and discuss protocols and may make one of three determinations:
**Approved:** The IBC may make a motion and vote to approve the protocol as submitted. The PI will then receive an approval letter signed by the IBC Chair.

**Deferred:** When additional information must be provided or requirements must be met prior to approval and project initiation. The IBC Secretary or other may contact the PI for additional information or to complete specific requirements prior to granting approval. Once the additional information has been received or requirements have been met the PI will receive the approval letter. The IBC will maintain deferred protocols for 6 months for the PI to meet the requirements for approval. After 6 months the protocol must be resubmitted to the IBC. The BSO acts as resources to assist the PI in this approval process.

**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.

The IBC Secretary will notify the researcher of the decision of the committee. An official letter of approval or reasons for disapproval, signed by the IBC Chair, will follow.

**Subcommittee Review**

**Teaching labs**

A subcommittee of the IBC will review teaching lab activities involving potentially biohazardous materials. As time allows these BAF submittals will be considered directly by the full committee. Faculty in teaching laboratories using potentially biohazardous materials will complete the BAF and provide amendments with a change in the use of materials. The IBC secretary will work with Department chairs to provide them with information on the status of BAF for teaching laboratories.

**Diagnostic labs**

A subcommittee of the IBC may be used to review diagnostic lab activities involving potentially biohazardous materials. As time allows these BAF submittals will be considered directly by the full committee.

**Transgenic plant field trials**

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 will be 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.).

Pre-proposal project initiation

During summer months or when a quorum of voting members of the IBC may not be available, PIs or supervisors may submit a pre-proposal for the purpose of the approval for initiation of work prior to full committee review. If initiation of work is approved, full review of the proposal will occur at the next opportunity for voting on the existing proposal or one modified in response to input from the sub-committee.

d. Voting requirements

Quorum required

A quorum of more than half of the voting membership is required to conduct business that involves voting on proposals or other documents under purview of IBC.

Full voting rights of all reviewing members

Each member has one vote.

No proxy votes

No proxy votes are allowed.

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.

Alternates

Each IBC member may have designated alternates that are approved by the IBC chair. The selected alternate may attend a given meeting, but has voting privilege only when the primary member is absent. An alternate that attends a meeting (when the primary member is present) does not count toward quorum and may not vote. Alternates are encouraged to review all protocols and participate in all discussions.

e. Communication from the IBC

To the investigator conveying IBC decisions

IBC actions that occur during meetings are promptly conveyed (usually within 5 days) to the PI signed in writing by the Chair or the Director of Research Integrity (if Chair is unavailable) and delivered by the IBC Secretary. Communications include approval or for deferred protocols all requirements that must be met
f. Appeal of IBC decisions

Criteria for appeal

If an IBC application is disapproved, the reasons for disapproval will be conveyed to the PI in writing. The investigator may request the IBC to reconsider by responding in writing, and may request an opportunity to appear before the IBC at the next monthly meeting.

XIII. IBC record requirements

a. IBC membership roster

Each year the IBC Secretary will submit to NIH-OBA (Office of Biotechnology Activities) 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) Manual. For a copy of this manual, please visit the IBC website (www.isu.edu/research/integrity/bio.shtml) or contact the Division for Research Integrity (282-2179) to request a copy.

c. Minutes of meetings

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

1) Members present
2) Others present (guests/consultants/researchers)
3) Summary of discussions
4) Motions made and seconded
5) Record of voting
6) Assurances that the current OBA Guidelines are adhered to

Per February 23, 2007 Guidelines

- IBC determines the appropriate containment per NIH Guidelines
- IBC assures that facilities, procedures, practices, training and expertise of personnel involved in rDNA research are appropriate.
The IBC periodically reviews recombinant DNA research to ensure compliance with the NIH Guidelines.

**IBC Minutes must include**

- Agent characteristics (e.g. virulence, pathogenicity, environmental stability)
- Types of manipulations planned
- Sources of the inserted DNA sequences (e.g. species)
- Nature of the inserted DNA sequences (e.g. structural gene, oncogene)
- Hosts and vectors to be used
- Whether an attempt will be made to obtain expression of a foreign gene and if so the protein that will be produced
- Containment conditions to be implemented
- Applicable section of the NIH Guidelines

**d. Retention of records**

All protocols reviewed and related materials will remain on file at the Division for Research Integrity (DRI) for three years after the completion of publication (or conclusion of the research). The IBC will maintain a database of all proposed and active projects and activities involving rDNA and potentially biohazardous material. Files may be paper or electronic.

The IBC files are not open to the public. Meeting minutes and IBC rosters will remain on file at the DRI as a record of the committee’s activities. These documents are accessible by the public.

Policy guidance and forms will be disseminated from and stored at the DRI until replaced by new and/or revised documents, as dictated by the ISU Records Retention policy.

**e. Communication to and from the IBC**

The BAF is available from the Division for Research Integrity or online at [www.isu.edu/research/integrity/bio.shtml](http://www.isu.edu/research/integrity/bio.shtml). Any questions regarding IBC review or the content of this Handbook should be directed to the Institutional Biosafety Committee Secretary at the Division for Research Integrity ibc@ISU.edu.

The Institutional Biosafety Committee Secretary keeps in contact with researchers regarding IBC decisions and requests for additional information.
XIV. Information the investigator provides to the IBC

a. Biosafety Approval Form (BAF)

A PI applying for IBC approval for research, or diagnostic activities needs to submit a completed BAF. In order for the application to be processed, it must be signed by the PI and any supplemental materials must be included. Supplemental materials may include a more detailed abstract, copies of APHIS permits or USDA/APHIS inspection results, or other information.

b. Deregulated Field Planting Registration Form (DFPRF)

A PI applying for IBC approval for planting deregulated items in the field must submit a completed Deregulated Field Planting Registration Form (DFPRF). It must be signed by the PI and other appropriate parties as designated on the form. Supplemental materials must include the technological agreement and a map of the planting site.

c. Teaching Activities

A PI applying for approval of teaching activities involved with potentially biohazardous material must contact the BSO. The BSO will assist the PI in developing appropriate biosafety training for students. The PI/Instructor is responsible for ensuring that students are all trained prior to working with the agents. The BSO will also act as a resource to assist the PI in developing a Biosafety Manual and performing a facility review.

d. Requests for amendments in activities after initial approval.

All modifications to currently approved research and diagnostics activities are required to have IBC review and approval prior to implementation. Minor changes that do not increase the risk to workers, the community, and/or the environment may be processed as an Administrative approval performed by the IBC Chair and the BSO. Significant modifications to approved activities will be forwarded to the full IBC for review. Amendments should be submitted on the BAF Amendment Form along with copies of the BAF sections to be modified or changed, as appropriate.

For changes in Teaching activities information pertinent to the modification should be sent to the IBC Secretary via email. These changes will be reviewed by the BSO and entered in the database and will only be brought to the teaching subcommittee if they increase the risk. The IBC Secretary will notify the BSO who will work with the IBC Chair to make this decision.

The IBC amendment approval is only good until the end of the original approval period. For example, if the original BAF approval is issued on January 1, 2013 it will have an expiration date of December
e. Reports of unexpected adverse events

All unanticipated/adverse events, as well as any actions taken on the part of the researcher as a response to the adverse event, should be reported to the IBC in writing. NIH Guidelines require that the PI report any significant events to the IBC & OBA (Office of Biotechnology Activities) (part of NIH) within 30 days.

f. Notification

Two months prior to the expiration of an approved protocol, the PI will receive an e-mail notifying them that their approved protocol is about to expire. Investigators desiring to continue their research are responsible for completing a new BAF and returning it to the IBC office in time for review before the expiration date. The investigator is responsible to keep each BAF current regardless of whether they receive an expiration notice or not.

One month prior to the expiration a second notification will be emailed. If the PI doesn’t respond at the end of two months the last notification will indicate that the protocol is expired. At this time all work on this project must be finished/discontinued.

g. Student Research

Research conducted by students involving biological materials, whether dissertation, thesis, or other research projects, must have a faculty PI. Students cannot serve as a PI on a BAF; the faculty advisor will be the PI on any project submitted to the IBC for review. IBC review and final approval should take place during the proposal stage of the dissertation or thesis.

XV. Biosafety laboratories (reviews, manuals and BBP Exposure Control Plans (ECP))

a. Biosafety laboratory reviews

The Technical Safety Office (TSO) reviews biosafety labs (BSL-2 and 3, ABSL-2 and 3) utilizing checklists and reports results and recommendations to the BSO and IBC. The IBC requires that BSL-2 facilities are inspected at least every three years and that BSL-3 facilities are inspected annually. The BSO reviews biosafety facilities used for recombinant DNA activities at BSL-1.

b. Biosafety manuals

The ISU Biosafety Officer works with the PI and ISU Technical Safety Office (TSO) to review biosafety manuals (templates can be found at the Biosafety website, www.bio-safety.ISU.edu/biosafety/forms.asp). The IBC considers the status of the laboratory specific biosafety
c. **State of Idaho Bloodborne Pathogen Standard (ECP)**

TSO is responsible for assisting the PI in adhering to this standard.

d. **Teaching Activities**

For teaching activities the PI or Instructor works with the BSO as a resource to develop student training for the course and the biosafety manual. The BSO will perform a facility review for BSL-1 facilities. TSO also performs BSL-2 facility reviews.

XVI. **Materials and activities requiring additional permits or approvals**

Many biological materials and activities require additional federal permits. These permits may be necessary for a wide range of activities. In general any biological material that requires a federal permit should be registered with the ISU IBC via the BAF, [www.isu.edu/research/integrity/bio.shtml](http://www.isu.edu/research/integrity/bio.shtml). Copies of the permits must accompany the BAF.

The following permits require the signature of the Institutional Official (Vice President for Research or designee)

a. **APHIS permits**

The United States Department of Agriculture (USDA) through the Animal and Plant Health Inspection Service (APHIS) issues permits for many biological materials and activities. Additional information can be found at the APHIS website [http://www.aphis.usda.gov/](http://www.aphis.usda.gov/).

b. **CDC permits**

The United States Department of Health and Human Services (DHHS) through the Centers for Disease Control (CDC) regulates many biological materials and activities. The CDC regulates the interstate transport of etiological agents. Additional information can be found at the CDC website [http://www.cdc.gov/od/ohs/biosfty/biosfty.htm](http://www.cdc.gov/od/ohs/biosfty/biosfty.htm).

c. **FDA permits**

d. **EPA permits**

e. **American Type Culture Collection (ATCC)**

Researchers ordering materials from ATCC for the first time may be required to complete a new account application. The ATCC account application requires the signature of an Institutional Official or the BSO.
f. Field trials of genetically modified organisms

Field trials of genetically modified organisms always require permits from the USDA Animal and Plant Health Inspection Service (APHIS). At ISU only the IO (the Vice President for Research or his/her designee) may sign permits for field testing of genetically modified organisms.

Additional requirements may be needed if the proposed field trials include transgenic plants expressing molecules of pharmaceutical intent (“bio-pharming”). There are specific regulations and requirements for the “Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds” (7 CFR Part 340).

Additional information can be found on the APHIS website (http://www.aphis.usda.gov/brs/pharmaceutical.html). All permits and field testing of plants designed to produce pharmaceuticals must be signed by the ISU IO (the Vice President for Research or his/her designee).

XVII. Bloodborne pathogens

Activities utilizing human and primate tissues, cells, blood and other potentially infectious body fluids must comply with Federal and State requirements. These materials are always considered to be potentially infectious agents and must be treated as a pathogen.

a. Activities where only exposure to potentially biohazardous material is through work with agents that fall under the Idaho BBP Standard

For this work to be in compliance the PI will work with TSO directly to develop the Exposure Control Plan (ECP). Requirement for additional submission of the appropriate BAF to the IBC for protocol approval is under the jurisdiction of the BSO in cooperation with the TSO.

b. Bloodborne pathogens program and training

At ISU the bloodborne pathogen program and training is administered by the TSO. Information can be found at the TSO website.

c. Biosafety level

In general research activities with human or primate blood and other body fluids should be performed using BSL-2 practices.

d. Human cell lines

Requirements for working with unfixed human cell lines are based upon whether the human cell line is comprised of primary explants, derived from these explants (typically those collected by a researcher or a colleague) or established, transformed human cell line lines well
characterized by rigorous techniques (such as those obtained from ATCC). When tissue from human cell lines is fixed with material to render it incapable of carrying an infectious agent these requirements may no longer apply.

**Primary Human & NHP Cells/Tissues**

Work with primary human cell lines requires adherence to the ISU Bloodborne Pathogen Program and the IBC. Work with unfixed primary human cell lines requires:

- Registration with the IBC via the BAF.
- Work with unfixed primary human cell lines must be performed in a BSL-2 facility following BSL-2 practices.
- A bloodborne pathogen exposure control plan must be in place.
- Bloodborne pathogen training is required.
- Individuals working with human cell lines should be offered hepatitis B immunization, unless information is available to indicate that hepatitis B is not reasonably expected to be present in the cell line.

**Established Human & NHP Cell Lines**

Even established or transformed cell lines (such as those obtained from the ATCC) may not be pathogen free as they can be adulterated with laboratory pathogens accidentally introduced by cultivation with other cell cultures or physically contaminated by other cell cultures handled in the same lab. Work with unfixed established human cell lines requires:

- Work with unfixed established human cell lines must be approved by the IBC using Form C. The Biosafety Level requirement for this work will be regarded at BSL-2 or above.
- Some established cell lines must be worked with in a BSL-2 facility. The cell line source and BSO should be consulted in establishing the appropriate biosafety level.
- An abbreviated bloodborne pathogen exposure control plan (for established human cell lines without characterized agents) is provided by TSO. For established cell lines with RG-2 or above characterized agents the BSO can provide an abbreviated bloodborne pathogen exposure control plan and assist the PI in developing a BSL-2 biosafety manual.
- Lab personnel training should include review of the biosafety manual and or ECP.
● If established cells or tissues were NOT derived from human or primate liver, Hepatitis B virus immunization need not be offered but will be considered for workers who request it.

XVIII. 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 for biological materials to be considered includes (but is not limited to):

● Additional locks (padlocks and electronic access cards) on laboratories, freezers, or other facilities where biological agents are used and/or stored.

● Chain-of-custody forms within laboratories to track materials.

● Inventories of biological materials. The inventory system of TSO is the presently accepted method of documentation of inventory.

● Logs of access to areas where biological materials are in use.

● Threat and/or vulnerability assessment from the TSO will be communicated to the IBC by the BSO.

XIX. Definitions

Potentially Biohazardous Material –

The Institutional Biosafety Committee reviews and approves many areas of biologically related research that may include, teaching, diagnostic, and extension activities.

The ISU IBC defines potentially biohazardous materials to include all of the categories below. Projects involving material(s) included in any of these categories must be submitted for IBC approval.

● Recombinant DNA (rDNA) or synthetic nucleic acids as detailed in Form A

● Genetically modified organisms. Including, but 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 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 such as; APHIS, CDC, FDA, EPA, etc.,

- 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 a material constitutes a potential biohazard, the IBC should be consulted. Questions should be directed to the Division for Research Integrity, IBC Secretary, or ISU Biosafety Officer.

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, platelets and wound exudates, and 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 (OPIM) 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) is an organism whose genetic material has been altered using techniques generally known as recombinant DNA technology.

**HIV:** Human immunodeficiency virus.

**Other potentially infectious materials (OPIM):** Including 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 an employee 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:** Defined in Idaho Administrative Code, Infectious or Biomedical Waste; any 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.
**Responsible Official:** A facility official who has been designated the responsibility and authority to ensure that the requirements of 42CFR73, 9CFR121, and 7CFR331 are met, as appropriate, for the pathogen/toxin in use.

**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. In this document, “Select Agents (SA) pathogens” and “SA pathogens” refer to both select agent pathogens and toxins for all biosecurity purposes.

**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 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 RO.

**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 arrive at 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.