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The WSU Institutional Biosafety Committee (IBC) Manual

Research Compliance Office and Institutional Biosafety Committee
Washington State University
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I. Introduction

The Washington State University (WSU) Institutional Biosafety Committee (IBC) is a Presidential Committee charged with protecting WSU faculty, staff, students, and visitors and has the authority and obligation to stop any activity that the committee believes to be unsafe. The **WSU Institutional Biosafety Committee (IBC) Manual** is your reference document detailing the policies and regulations governing research with biological materials and the requirements for submitting research proposals for review by the WSU IBC. The instructions and information contained in this handbook are set forth and adopted by the WSU IBC and are based on federal, state, county, and University regulations and guidelines.

Sections of the manual describe and explain the various aspects of the review process and regulatory requirements. Investigators and IBC committee members should familiarize themselves with the contents of this handbook. In addition, investigators should carefully review the 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. All research, teaching, diagnostic, and extension activities performed by faculty, students, visitors (including non-WSU employees working in WSU facilities), or employees of WSU involving recombinant DNA (rDNA) and/or potentially biohazardous materials are reviewed and approved by the IBC. These requirements also apply to all activities in/on WSU land, facilities (owned, leased, or rented) and/or WSU designated or sponsored activities. The IBC is comprised of faculty representatives, from various academic disciplines at WSU, researchers, non-scientific members, representatives from University departments, students, 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, complete openness, and honesty by upholding the highest ethical principles in the conduct of research. By upholding the highest standards, we build public support for the pursuit of greater knowledge in a safe research environment.

Biosafety is a team effort involving the Principal Investigator (PI), laboratory research and support staff, Biosafety Committee members, Environmental Health and Safety, Risk Management, Animal Care and Use, Human Subjects, and Radiation Safety, and is inextricably linked to the 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 Principal Investigator's responsibility to become thoroughly familiar with the contents of this manual, to make sure that his or her workers become equally familiar with it, and to ensure that all work with potentially biohazardous materials is conducted in a safe and ethically sound manner, in accordance with the WSU Safety Policies and Procedures Manual (SPPMs), laboratory specific biosafety manuals and Standard Operating Procedures (SOPs).

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, the services and resources of the Research Biosafety Officer and the Department of Environmental Health & Safety (EH&S) are available.
II. The Institutional Authority Under Which the IBC is Established
The Washington State University Institutional Biosafety Committee (IBC) is a Presidential Committee. The Institutional Official (IO) for the IBC is the Vice Provost for Research.

III. Purpose of the IBC
The Institutional Biosafety Committee oversees and establishes University policy for review and approval of all research involving the use of recombinant DNA and potentially biohazardous materials (see section IV for complete list of potentially biohazardous materials) to assure compliance with current federal regulations and guidelines. Principal Investigators and/or laboratory supervisors at Washington State University who either store or carry out experiments involving potentially biohazardous materials must inform the Institutional Biosafety Committee via the Biosafety Approval Form (BAF). The Biosafety Approval Form (BAF) is available from the Research Compliance Office or on the Internet at [www.ogrd.wsu.edu/Forms.asp](http://www.ogrd.wsu.edu/Forms.asp).

It is the policy of the University that all research, teaching, diagnostic, and extension activities* involving potential biohazards be conducted in a safe manner in order to protect laboratory workers, students, other persons and the environment from potentially biohazardous agents and in such a manner that research projects conducted by one faculty member will not have an adverse effect on adjacent projects conducted by other scientists. The WSU IBC will maintain all related records for 3 years after the completion of the research activity.

Further, it is University policy that no Risk Group 4 Agents may be used or stored at WSU. See the NIH Guidelines and CDC BMBL for a list of these agents.

* Throughout this document the terms “research” and/or “protocol” are intended to be synonymous with “research, teaching, diagnostic, and extension activities.

IV. Research and Activities Requiring Review and Approval from the IBC
The Institutional Biosafety Committee reviews and approves many areas of biologically related research, teaching, diagnostic, and extension activities.

The WSU IBC defines potentially biohazardous materials to include all infectious organisms (bacteria, chlamydiae, fungi, parasites, prions, rickettsias, and viruses) which can cause disease in
humans, animals, or plants, or cause significant environmental or agricultural impact. In addition, work with materials that may harbor infectious organisms, such as human or primate tissues, fluids, cells, or cell cultures are also included.

Potentially biohazardous materials* include (but are not limited to) all of the categories below. Projects involving material(s) included in any of these categories must be submitted for IBC approval prior to initiating the research.

- Recombinant DNA (rDNA),
- Genetically modified organisms. Including, but not limited to:
  - Animals, plants, invertebrates, and/or other organisms created by WSU employees or in/on WSU property,
  - Transgenic field trials, any genetically modified organisms to be introduced into the environment (by WSU personnel and/or on WSU property),
  - Field testing of plants engineered to produce pharmaceutical and industrial compounds,
- Any organisms, agents, or toxins requiring federal permits (including but not limited to, APHIS, CDC, EPA, FDA, ...),
- Pathogens/infectious agents (human, animal, plant, and other),
- 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 Research Compliance Office for additional information,
- Biological toxins,
- Human blood and potentially infectious human fluids or tissue (see section XVII.c for more information),
- Work with animals or vectors known or suspected to be reservoirs of BL2 or BL3 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 whether a material constitutes a
potential biohazard, the IBC should be consulted. Questions should be directed to the Research Compliance Office (335-1585), IBC Coordinator (335-9661), or Research Biosafety Officer (335-9661).

* 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 considered biohazardous.

In addition to regulation of activities with potentially biohazardous materials, the WSU 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.

V. Principles Which Govern the IBC

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

- 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.
- WAC 296-823 Bloodborne Pathogens

No experiment should be considered so important that it jeopardizes the well-being of the worker or the environment. The planning and implementation of safety protocols to prevent laboratory-acquired
infections and to eliminate the spread of contamination must be part of every laboratory's routine activities and biosafety manual.

The handling of biological agents and recombinant DNA requires the use of precautionary measures dependent on the agents involved and the procedures being performed. 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.

VI. Duties and Responsibilities

a. Principal Investigators and Laboratory Supervisors

Principal Investigators (PI's) are primarily responsible for the people and activities in their laboratories. They are responsible for implementing an appropriate biological safety program specific for their projects (including having a current Biosafety Manual for the individuals and activities under their purview).

They should evaluate all their operations, perform risk assessments, and develop plans for all activities accordingly. They are responsible for establishing the appropriate biological safety containment levels in consultation with the WSU Research Biological Safety Officer and ensuring adherence to these levels. They must also ensure strict adherence to biological safety practices and techniques for all work involving potentially biohazardous materials. Individuals are responsible for their own safety and that of others potentially affected by biohazardous agents or substances, and for the protection of the environment.

Prior to the commencement of any activities involving the use of potentially biohazardous materials, the PI must register the potentially biohazardous agents they propose to use with the IBC via the Biosafety Approval Form (BAF). It is also the responsibility of the PI to 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.
b. Laboratory Workers, Postdocs, Students, 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.

Whoever works in the laboratory 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 person must look out for her/his own safety and that of their co-worker. If individuals do not follow the university and laboratory-specific biosafety practices and procedures in the conduct of their laboratory duties, we cannot have a safe working environment. It is the laboratory worker’s responsibility to:

- Conscientiously follow lab-specific biosafety practices and procedures.
- Inform the Principal Investigator of any health condition that may be a result of or complicated by their work in the lab.
- Report to the Principal Investigator or the lab supervisor all problems, procedural discrepancies, spills, or accidental releases as soon as they occur.
- Report to the Research Compliance Office any significant violations in biosafety policy, practices, or procedures that are not resolved by the Principal Investigator.
- Refuse to take any adverse action against any person for reporting real or perceived problems or violations of procedures to supervisors, the Principal Investigator, the Research Compliance Office or members of the Institutional Biosafety Committee.

c. Department Leaders (Deans, Chairs, and Directors)

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

- Require that prior to initiation of research, each investigator or laboratory director using recombinant DNA, microbial pathogens
or human blood and tissues, completes and submits the IBC Biosafety Approval Form (BAF).

- Require that students receive instruction in safety procedures in teaching laboratories or field situations 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 department.

d. 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 Washington State University. The IBC also assists EH&S 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 WSU, researchers, non-scientific members, students, and community representatives who are not affiliated with the university. The Committee typically meets monthly to review research and other activities submitted on the BAF.

The Institutional Biosafety Committee can be reached by contacting the Research Compliance Office, at (509) 335-9661 (www.research-compliance.wsu.edu).

e. The Research Biosafety Officer (BSO)

The BSO is responsible for developing, leading, directing, and managing a comprehensive biological safety program throughout all laboratories at Washington State University. The biological safety program must meet NIH, CDC, USDA, OSHA, any other granting agency, and Federal and State requirements. The program includes close cooperation and interaction with faculty committees approving research protocols and procedures for the 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 complete list). The BSO interacts with the WSU research, teaching, diagnostic, and extension community to
inform and ensure compliance with state and federal reporting or audit requirements, and effect actions to inspect and correct deficiencies when noted.

f. The WSU Department of Environmental Health and Safety (EH&S)

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

- Inspects (initial and at regular intervals) physical facilities and containment equipment for compliance with general CDC guidelines for Biosafety Level (BSL) and Animal Biosafety Level (ABSL) laboratories in accordance with laboratory inspection checklists developed in coordination with the WSU Biosafety Officer and the IBC,

- Coordinates with Facilities Operations and the biosafety officer for corrections/modifications/repairs to physical facilities,

- Assists the biosafety officer in review of 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 biosafety officer and 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 outside of laboratory buildings and are treated and disposed of properly after leaving these buildings per applicable state and federal regulations,

- Maintains list of approved biosafety laboratories with inspection dates and results. The IBC requires that BSL-2 facilities are inspected at least every three years and that BSL-3 facilities are inspected annually.

- Works with Principal Investigators and the research Biosafety Officer in the review and approval of biosafety manuals. Templates can be found at the EH&S website, www.ehs.wsu.edu.

- Maintains programs and educational materials pertaining to laboratory safety.
• Implement bloodborne pathogen standard medical surveillance program.

VII. Authority of the IBC

a. **Scope of authority defined**
   The WSU IBC has the authority to approve, require modifications in, 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 WSU IBC approves protocols for up to three years. After three years the research protocol (BAF) must be resubmitted. Research that has been reviewed and approved by the WSU IBC may be subject to further review and disapproval by the Institutional Official (President, Provost, or Vice Provost for Research). However, those officials may not approve research if it has been disapproved by the WSU IBC.

   The WSU IBC also functions independently of other committees and makes its independent determination whether to approve or disapprove the protocol based upon whether or not biological safety aspects adhere to relevant regulations, guidelines, and policies. The WSU IBC has jurisdiction over all research involving regulated or potentially hazardous biological materials, thereby providing broader protection than required by the 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 WSU IBC review and must be reevaluated 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 a BAF Amendment form.

   An amendment may require full IBC review if the modification is significant. Examples of significant amendments may include; a change in PI, the addition of potentially biohazardous materials that require a higher biosafety level, and the addition of materials
or procedures that may increase the risks of the research. Minor amendments may be approved by the Chair of the IBC and/or the research Biosafety Officer. Examples of minor amendments may include the addition of very similar potentially biohazardous materials to an approved protocol, change of laboratory room (if change is to an equivalent and approved facility), addition of personnel on the protocol, and change of PI contact information.

The IBC modification approval is only good until the end of the original approval period. For example, if the BAF original approval is issued on January 1, 2008 it will have an expiration date of December 31, 2010. If a modification is approved during this time, the approval still lasts only until December 31, 2010.

e. Authority to suspend or terminate approval of a study
The WSU IBC has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IBC’s 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 IBC's action and shall be reported promptly to both the PI and department head.

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

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 biohazardous materials and rDNA commonly conducted at WSU.

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 recombinant DNA research, teaching, diagnostic, and extension activities and to identify any potential risk to workers, public health, or the environment.

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

The Research Biological Safety Officer (BSO) will be a voting member.

Every effort will be made to include 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.

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

Every effort will be made to include a voting member from the Office of the Campus Veterinarian (OCV).

Every effort will be made to include a non-voting member from EH&S.

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

Every effort will be made to include representation from the urban campuses on the IBC.

IX. Management of the IBC

a. The Chair

i. Selection and appointment
The Chair is appointed by the President based upon the recommendation of the Institutional Official. 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 be a substitute. If a Chair is unavailable for a period of time exceeding 3 months the Institutional Official may appoint a temporary Chair.

ii. Duties
The Chair directs the IBC meetings in accordance with institutional and federal requirements. S/he works closely with IBC members, the Institutional Official, the Research Compliance Officer, the IBC coordinator, the Research Biosafety Officer, EH&S, and investigators to ensure that research and other activities involving regulated or potentially biohazardous materials are conducted safely and in accordance with all applicable federal, state, and Institutional regulations, policies, and procedures. The chair is the designated signatory for the IBC and conducts all IBC meetings. The Chair may delegate signatory duties to Research Compliance Office personnel.

The Chair counts toward quorum at meetings and also votes.

iii. Removal
The Chair may be removed or replaced by the Institutional Official.

b. The IBC members

i. Selection and appointment
Members are appointed by the President based upon the recommendation of the Institutional Official. WSU faculty members appointed to the IBC will serve on the board for a three-year term. Appointments to the committee typically begin August 16th of the year appointed and end August 15th three years later.

Community and/or non-affiliated IBC members will be appointed to the board for three-year terms.

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.

ii. Duties
WSU 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.

iii. Removal
IBC members may be removed or replaced by the Institutional Official.

c. Training of IBC Chair and members

i. Orientation
When a new member or chair is appointed to the IBC, the Research Compliance Officer, the Research Biological Safety Officer, and/or the IBC Coordinator will hold a New Member Orientation. This orientation will introduce these new members to the federal regulations, WSU IBC meeting procedures, review process, and the Biosafety Approval Form (BAF).

ii. 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. The IBC Coordinator, Research Biological Safety Officer, and Research Compliance Officer may attend professional development conferences throughout the year to keep current on IBC issues.

iii. Reference Materials
Each IBC member is given a WSU IBC Manual which includes the specific WSU IBC Policies and Procedures.

d. Liability coverage for IBC members
State law offers protection for state employees and authorized volunteers who are sued for duties and actions performed in the course of their employment and in good faith.
e. Use of consultants
The WSU IBC is encouraged to use non-member consultants for advice and information in specialized areas as needed. These consultants may be WSU faculty or staff, or may be unaffiliated with WSU. The consultants may present their assessments in writing or in person.

f. Administrative support staff
The WSU IBC has an IBC Coordinator to coordinate the privileged and confidential institutional review and approval process of proposed research activities involving biological materials.

The IBC Coordinator

- Presents evaluations, recommendations, historical information and precedents regarding compliance with laws, regulations, and ethical and safety standards;
- Assists in the interpretation and application of Federal and State laws, regulations and institutional policies and guidelines relevant to the use of biological materials in research proposals and other activities;
- Communicates committee requests to investigators for additional Information and revisions and review responses;
- Prepares correspondence, reports, agendas, and certifications of review for funding agencies related to review and approval process;
- Independently reviews and approves administrative and procedural modifications (in consultation with the Chair, BSO, and/or RCO as needed);
- Facilitates approval for emergency or unique opportunity situations;
- Advises faculty, staff, and students in preparation of applications for research proposals and other activities involving biological materials;
- 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 on the BAF. The Conflict of Interest Committee will review the financial disclosure, and consider the potential conflict of interest (as outlined in OGRD Memorandum No. 3, *WSU Policy and Procedures for Managing Conflict of Interest in Sponsored Research and Scholarship*).

After the Conflict of Interest Committee determines 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.

In all cases, good judgment, openness of process and reliance upon objective, third party oversight can effectively safeguard the integrity of the research.

b. Non-Financial Conflict of Interest

i. No selection of IBC members by investigators
Principal Investigators cannot select which IBC member will review their protocol. Additionally, any IBC member must recuse himself or herself from a review if s/he has any real or apparent conflict of interest.

ii. 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 an active role or conflict of interest. Failure to abide by these provisions may be cause for removal of a member from the IBC.

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. The IBC member must make any conflict of interest known to the IBC Chair. The member may provide information to
the IBC if requested. The fact that a protocol is submitted by another investigator from an IBC member's Department 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 WSU IBC is responsible for the review and approval of all projects (whether funded or non funded) involving regulated or potentially biohazardous materials conducted under the auspices of Washington State University regardless of funding source.

b. Reporting findings and actions of the IBC to the investigator
   The IBC Coordinator will report findings and actions of the IBC to the investigator.

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.

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 a BAF Amendment form.

   The IBC modification approval is only good until the end of the original approval period. For example, if the BAF original approval is issued on January 1, 2008 it will have an expiration date of December 31, 2010. If a modification is approved during this time, the approval still lasts only until December 31, 2010.

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 Principal Investigator 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 Research Compliance Office in writing of the change, within 72 hours, and include a written description of the change and events which necessitated immediate implementation.

f. Ensuring prompt reporting to the IBC of unanticipated problems
The IBC Coordinator or the Research Compliance Officer will report in writing within 10 working days to the IBC Chair, Vice Provost for Research, relevant Department or Agency Head (sponsor), any applicable regulatory body, any report of adverse events as mandated in the Federal Regulations. Select Agents and Toxins require immediate notification of the Responsible Official (the Vice Provost for Research) and the relevant agency (CDC or APHIS).

XII. Operations of the IBC

a. Scheduling of meetings
The full IBC will convene monthly throughout the 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 Coordinator. IBC meetings are open to the public and meeting dates for the current semester are published on the Research Compliance Office’s website.

b. Pre-meeting distribution of IBC review materials to members
Seven calendar days prior to a monthly meeting the IBC coordinator will send to each committee member who will be in attendance at the next meeting:

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

i. Description of the review process
The WSU IBC is responsible for the review and approval of all projects involving potentially biohazardous materials conducted under the auspices of Washington 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.

ii. Review

Pre-Review
Upon receipt of a protocol, the IBC coordinator and/or Biological Safety Officer will pre-review the protocol for required signatures and completion. The coordinator or BSO will contact the investigator via phone or email if any additional materials are required.

Committee Review
The IBC Chair and/or Coordinator will assign committee members as primary and secondary reviewers. Primary and secondary reviewers should carefully review each protocol assigned and clarify any questions/discrepancies/concerns with the Principal Investigator prior to the scheduled IBC meeting. All committee members are expected to review all protocols. All protocols will be discussed in detail at convened meetings.

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

i. Approved: The IBC may make a motion and vote to approve the protocol as submitted. The PI will then receive an approval letter.

ii. Deferred: When additional information or requirements must be met prior to approval. The IBC coordinator or other may contact the PI for additional information or to complete specific requirements prior to granting approval. Once the additional information or requirements have been met the PI will receive the approval letter. The IBC will maintain deferred protocols for a maximum of 6 months for the PI to meet the requirements for approval. After 6 months the protocol must be resubmitted to the IBC.
iii. **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 Coordinator will notify the researcher of the decision of the committee and, in the case of approved protocols, issue written approval on behalf of the committee.

**Expedited Review**
The IBC Chair may agree to expedite the review of a particular protocol when extenuating circumstances warrant. If the IBC Chair agrees to expedite a review, the entire protocol will be sent (either electronically or paper) to all committee members. Committee members will return any question/comments to the IBC Coordinator to be clarified by the Principal Investigator. All such communications will be shared with the entire committee membership. Committee members will return their vote to approve, defer, disapprove, or discuss at a convened committee meeting to the IBC Chair and/or Coordinator.

d. **Subcommittee Review**
The IBC will use subcommittees to facilitate reviews in certain circumstances. Subcommittees will be composed of 2 to 4 individuals with the appropriate expertise. When subcommittees are used for review the subcommittees will report to the full committee. Subcommittees will assist in reviews requiring more specialized review or in cases where sensitive materials or information may be discussed (select agents, confidential business information, …).

The subcommittee will approve or disapprove the protocols in the specific situations listed below. This only applies if the activity does not involve recombinant DNA (recombinant DNA activity requires full committee review). The subcommittee will report to the full committee on protocols reviewed and the subcommittees decision.

i. **Teaching labs**
A subcommittee of the IBC will review all teaching activities involving potentially biohazardous materials.
ii. Diagnostic labs
   A subcommittee of the IBC will review all diagnostic lab activities involving potentially biohazardous materials.

iii. Select agents and toxins
   A subcommittee of the IBC will review all select agent and toxin activities.

iv. Transgenic plant field trials
   A subcommittee of the IBC will review all transgenic field trials.

e. Voting requirements

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

ii. Full voting rights of all reviewing members
   Each member has one vote.

iii. No proxy votes
   No proxy votes are allowed.

iv. 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.

v. Alternates
   Each IBC member may have designated alternates. 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.
f. Communication from the IBC

i. To the investigator conveying IBC decisions
IBC actions that occur during meetings are promptly conveyed (usually within 5 days) to the Principal Investigator in writing by the IBC Coordinator. Communications include approval or for deferred protocols all requirements that must be met for the committee to grant approval.

g. Appeal of IBC decisions

i. 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.

XIII. IBC Record Requirements

a. IBC membership roster
Each year the IBC coordinator 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 WSU Institutional Biosafety Committee (IBC) Manual. For a copy of this manual, please visit the Research Compliance Office website (http://www.bio-safety.wsu.edu/) or contact the Research Compliance Office (335-9661) to request a copy.

c. Minutes of meetings
The IBC Coordinator 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
d. **Retention of records**
All protocols reviewed and related materials will remain on file at the Research Compliance Office (RCO) for three years after the completion of publication (or 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 the RCO as a record of the committee’s activities.

Policy guidance and forms will be disseminated from and stored at the RCO until replaced by new and/or revised documents.

e. **Communication to and from the IBC**
The Biosafety Approval Form (BAF) is available from the Research Compliance Office or on the internet at [www.ogrd.wsu.edu/Forms.asp](http://www.ogrd.wsu.edu/Forms.asp). Any questions regarding IBC review or the content of this Handbook should be directed to the Institutional Biosafety Committee Coordinator at the Research Compliance Office.

The Institutional Biosafety Committee Coordinator 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)**
Researchers applying for review need to submit a completed Biosafety Approval Form (BAF). In order for the application to be processed, it must be signed by the researcher and the Department Chair or Dean and any supplemental materials must be included. Supplemental materials may include a more detailed abstract, copies of APHIS permits or USDA/APHIS inspection results, etc…. BAFs must be submitted for all research, teaching, and diagnostic activities.

b. **Requests for modification in study after initiation**
All modifications to currently approved research are required to have IBC review and approval prior to implementation. Minor changes that do not increase the risk to research participants, the community, and/or the environment may receive an expedited review performed by the IBC Chair, BSO, and/or Coordinator.
Significant modifications to approved protocols will be forwarded to the full IBC for review. Modifications are typically accomplished by submitting the BAF Amendment form or copies of the BAF sections to be modified/changed.

The IBC modification approval is only good until the end of the original approval period. For example, if the original BAF approval is issued on January 1, 2008 it will have an expiration date of December 31, 2010. If a modification is approved during this time, the approval still lasts only until December 31, 2010.

c. Reports of unexpected adverse events
All unanticipated/adverse events should be reported to the IBC in writing as well as any actions taken on the part of the researcher as a response to the adverse event.

d. Three year renewal/project expiration
Two months prior to the expiration of an approved protocol, the Principal Investigator will receive a letter/e-mail notifying them that their approved BAF 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 BAFs current regardless of whether they receive an expiration notice or not.

e. Student research
Student initiated research involving biological materials, whether dissertation, thesis, or other research projects, should be supervised by a faculty advisor and 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 (inspection and manuals)

a. Biosafety laboratory inspection
The WSU Environmental Health and Safety Department (EH&S) inspects biosafety labs (BSL-2 and 3, ABSL-2 and 3) utilizing checklists and reporting 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.
b. **Biosafety manuals**
The Research Biosafety Officer works with Principal Investigators and WSU Environmental Health and Safety Department (EH&S) to review biosafety manuals (templates can be found at the EH&S website, [www.ehs.wsu.edu](http://www.ehs.wsu.edu)). The IBC considers the status of the laboratory specific biosafety manual when reviewing and approving protocols.

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 WSU IBC via the Biosafety Approval Form (BAF, [www.ogrd.wsu.edu/Forms.asp](http://www.ogrd.wsu.edu/Forms.asp)).

The following permits require the signature of the Institutional Official (the Vice Provost for Research or his/her 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 Biosafety Officer.
f. Field trials of genetically modified organisms (APHIS)
Field trials of genetically modified organisms always require APHIS permits. At WSU only the Institutional Official (the Vice Provost for Research or his/her designee) may sign permits for field testing of genetically modified organisms.

An additional area of field trials that includes increased requirements is the area of 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 WSU Institutional Official (the Vice Provost for Research or his/her designee).

XVII. Bloodborne Pathogens
Research activities utilizing blood or other potentially infectious bodily fluids must comply with federal and State requirements. Blood and other bodily fluids are always considered to be infectious agents and must be treated as a pathogen.

a. Bloodborne pathogens program and training
At WSU the bloodborne pathogen program and training is administered by the EH&S department. Information can be found at the EH&S website (http://www.ehs.wsu.edu/biosafety.asp).

b. Biosafety level
In general research activities with blood and other bodily fluids must be performed in a BL2 laboratory.

c. Human cell lines
Requirements for working with unfixed human cell lines are based upon whether the human cell line is 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 no longer apply.
i. Primary Human Cell Lines
   Work with primary human cell lines requires adherence to the WSU Bloodborne Pathogen Program. 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 BL2 facility following BL2 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.

ii. Established Human Cell Lines
   Even established or transformed cell lines (such as those obtained from the American Type Culture Collection (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 should generally be performed following BL2 practices.
   - An abbreviated bloodborne pathogen exposure control plan included as part of a BSL2 biosafety manual is considered adequate.
   - Lab personnel training should include review of the biosafety manual and appendix.
   - If established cells or tissues were NOT derived from human or primate liver, Hepatitis B virus immunization need not be offered.

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, 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.

XIX. Definitions

Potentially Biohazardous Material –

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

The WSU IBC defines potentially biohazardous materials to include all infectious organisms (bacteria, chlamydiae, fungi, parasites, prions, rickettsias, and viruses) which can cause disease in humans, animals, or plants, or cause significant environmental or agricultural impact. In addition, work with materials that may harbor infectious organisms, such as human or primate tissues, fluids, cells, or cell cultures are also included.

Potentially biohazardous materials 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),
- Genetically modified organisms. Including, but not limited to:
  - Animals, plants, invertebrates, and/or other organisms created by WSU employees or in/on WSU property,
  - Genetically modified whole plants (even those commercially available and not requiring APHIS permits),
  - Transgenic field trials, any genetically modified organisms to be introduced into the environment (by WSU personnel and/or on WSU property),
Field testing of plants engineered to produce pharmaceutical and industrial compounds,

- Any organisms requiring federal permits (APHIS, CDC, FDA, EPA, ...),
- Pathogens/infectious agents (human, animal, plant, and other),
- Select/Biological Agents and Toxins (CDC and USDA),
- Biological toxins,
- Human blood and blood products, human bodily fluids, and/or human tissue,
- Work with animals or vectors known or suspected to be reservoirs of BL2 or BL3 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 Research Compliance Office, IBC Coordinator, or Research 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 blood, human blood components that include plasma, platelets and wound exudates, and products made from human 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 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.

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 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 to be personal protective equipment.

Regulated waste: Defined in Washington Administrative Code, 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.