



**MONTANA  
STATE UNIVERSITY**

**I B C**

**Institutional Biosafety Committee  
Manual**

## Contents

Certification and Approvals .....	4
IBC Mission Statement.....	5
Purpose of the IBC .....	5
Activities Requiring an IBC Protocol .....	6
Principles which Govern the IBC.....	7
Duties and Responsibilities .....	8
Principal Investigators and Laboratory Supervisors .....	8
Laboratory Workers .....	8
Institutional Biosafety Committee (IBC) .....	9
Biosafety Officer (BSO) .....	10
IBC Program Manager.....	11
Safety and Risk Management .....	11
Authority of the IBC .....	12
Scope of authority.....	12
Approve, return for modification to secure approval, withhold approval, or suspend.....	12
Annual Renewals.....	12
Review of Amendments.....	12
Suspension or termination of approved projects.....	13
IBC Membership.....	14
Committee Size .....	14
Qualification.....	14
Representation .....	14
Management of the IBC.....	15
IBC Chair .....	15
<b>Appointment</b> .....	15
<b>Duties</b> .....	15
<b>Removal</b> .....	16
IBC members.....	16
<b>Selection and Appointment</b> .....	16
<b>Duties</b> .....	16
<b>Removal</b> .....	16
IBC Training .....	16
<b>Orientation</b> .....	16
<b>Continuing Education</b> .....	16

<b>Reference Materials</b> .....	16
<b>Use of Consultants</b> .....	17
Conflict of Interest Policy.....	17
Recusing of Voting Members.....	17
Operation of the IBC.....	18
Scheduling of meetings.....	18
The Review Process.....	18
<i>Review of submitted protocols:</i> .....	18
Voting requirements.....	19
<i>Quorum required</i> .....	19
<i>Full voting rights of all reviewing members</i> .....	19
<i>No proxy votes</i> .....	19
<i>Prohibition of conflict-of-interest voting</i> .....	19
Communication from the IBC.....	20
<i>To the investigator conveying IBC decisions</i> .....	20
IBC Record Keeping Requirements.....	20
IBC membership roster.....	20
Written procedures and guidelines.....	20
Minutes of meetings.....	20
Retention of records.....	21
Communication to and from the IBC.....	21
PI Responsibilities.....	22
IBC protocol.....	22
IBC amendments.....	22
Reports of unanticipated adverse events.....	22
Notification.....	23
Biosafety Laboratories:.....	24
Inspections, manuals, OSHA BBP Exposure Control Plan.....	24
Biosafety laboratory inspections.....	24
Biosafety manuals.....	24
Teaching Activities.....	24
Materials and Activities Requiring Permits or Approvals.....	25
APHIS permits.....	25
CDC permits.....	25
American Type Culture Collection (ATCC).....	25
Field trials of genetically modified organisms.....	25
Bloodborne Pathogens.....	26
Activities that deal exclusively with agents covered under the OSHA BBP standard.....	26
Bloodborne pathogens program and training.....	26
Biosafety level.....	26
Human cell lines.....	26
<b><i>Primary Human and NHP Cells/Tissues/Established Human and NHP Cell Lines</i></b> .....	27
Biosecurity.....	27
Contact Information.....	28

# Certification and Approvals

\_\_\_\_\_  
**Signature of IBC Chair** \_\_\_\_\_  
**Date**

Mike Babcock

\_\_\_\_\_  
**Print Name**

\_\_\_\_\_  
**Signature of Director of Research Compliance** \_\_\_\_\_  
**Date**

Kirk Lubick

\_\_\_\_\_  
**Print Name**

\_\_\_\_\_  
**Signature of Biosafety Officer** \_\_\_\_\_  
**Date**

Phil J. Merta

\_\_\_\_\_  
**Print Name**

<b>Previous Review Dates</b>
1/27/2015

## IBC Mission Statement

The mission of the Institutional Biosafety Committee (IBC) at MSU is to ensure that activities with biohazardous material are conducted safely and responsibly. To fulfill this commitment, the IBC reviews and monitors all research and teaching activities by faculty, staff, and students that utilize infectious agents, human body fluids or tissues, and recombinant or synthetic nucleic acid molecules.

The IBC is comprised of faculty representatives from various academic disciplines at MSU, researchers, non-scientific members, and community representatives who are not affiliated with the university. The committee typically meets monthly to review research protocols and other submitted materials.

### Purpose of the IBC

The IBC oversees and establishes MSU policy for review and approval of activities involving the use of potentially biohazardous materials and recombinant DNA (rDNA), to ensure compliance with current federal regulations and guidelines (see [BMBL](#) and [NIH Guidelines](#)). Principal Investigators (PI) and/or laboratory supervisors who perform research, teaching, or diagnostic activities that involve the use or storage of these agents must submit an IBC protocol for review and approval by the committee.

All activities involving potentially biohazardous materials must be conducted in a safe manner to ensure the protection of laboratory workers, students, community, and environment. IBC-mandated biosafety practices such as facility engineering (e.g. biosafety cabinets, directional airflow), personal protective equipment (PPE; e.g. lab coats, safety glasses, gloves), standard operating procedures (SOP's; e.g. standardized emergency, experimental methods), and administrative controls (e.g. training, occupational health, lab inspections etc.) ensure the proper biocontainment of the agent(s) under study. The IBC works in conjunction with the Office of Research Compliance (ORC) to promote and ensure MSU's adherence to all applicable regulatory and recordkeeping requirements.

Risk Group (RG) 4 Agents cannot be used or stored at MSU. RG4 Agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. See the Center for Disease Control's [BMBL](#) and the [NIH Guidelines](#) for a list of these agents.

## Activities Requiring an IBC Protocol

The IBC reviews and approves many laboratory activities which may include research, teaching, and diagnostic activities.

All activities (e.g. research, teaching, diagnostic) conducted/performed at MSU, or funded by a grant awarded to an MSU PI which conform to the descriptions listed below must submit an IBC protocol.

The IBC defines potentially biohazardous materials to include all infectious organisms (bacteria, chlamydia, parasites, prions, rickettsia, and viruses), toxins, and rDNA which can cause disease or illness in humans, animals, or plants, or cause significant environmental or agricultural impact. Materials that may harbor infectious organisms, such as human or primate tissues, fluids, cells, or cell cultures are also considered biohazardous.

Projects involving materials included in any of these categories must secure IBC approval prior to initiation:

- Recombinant DNA (rDNA).
- Genetically modified organisms (GMOs) including, but not limited to:
  - Animals, plants, invertebrates, and/or other organisms created by MSU employees or in/on MSU property.
  - Transgenic field trials, any genetically modified organisms to be introduced into the environment, including planting of deregulated items in the field.
  - Field testing of plants engineered to produce pharmaceutical and industrial compounds.
- Pathogens/infectious agents and pests (RG2/BSL2 or higher human and animal pathogens, non-indigenous plant pathogens as well as those plant and animal pests regulated by the USDA-APHIS.
- Select/Biological Agents and Toxins (CDC and USDA). Please note that possession, use, or transfer of Select Agents and Toxins entails additional requirements –contact the ORC for additional information.
- Human and non-human primate cells (including cell lines), tissue, blood 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.
  - Any work that requires a USDA-Animal and Plant Health Inspection Service ([APHIS](#)) permit; in order to protect American agriculture and our natural resources, APHIS oversees and regulates the “import, transit and release of regulated animals, animal products, veterinary biologics, plants, plant products, pests, organisms, soil, and genetically engineered organisms.”

## Principles which Govern the IBC

The IBC operates in accordance with the following regulations/guidelines:

- [NIH Guidelines](#) for Research Involving Recombinant DNA Molecules (NIH guidelines).
- Biosafety in Microbiological and Biomedical Laboratories ([BMBL](#)).
- [USDA/APHIS 7 CFR Part 340](#), Introduction of Organisms and Products Altered or Produced Through Genetic Engineering and all APHIS Permit regulations/guidelines.
- [42 CFR Part 73](#), Possession, Use, and Transfer of Select Agents and Toxins.
- [7 CFR Part 331](#) and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins.
- [29 CFR 1910.1030](#) Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard.

No work should be considered so important or valuable as to jeopardize the well-being of personnel, the environment, or the community. Planning and implementation of safety protocols to prevent laboratory-acquired infections and 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 performed. The purpose of this manual is to provide information and guidance for use in conjunction with other resources for the evaluation, containment, and control of potentially biohazardous materials in laboratories.

# Duties and Responsibilities

## ***Principal Investigators and Laboratory Supervisors***

Principal Investigators (PI) are responsible for the conduct of people and activities in their laboratories. PI's and Laboratory Supervisors are responsible for implementing an appropriate biological safety program based on their specific project needs.

PI responsibilities include:

- Evaluation of operations.
- Performance of risk assessments.
- Development of biosafety plans and SOPs for all applicable activities.
- Establishment of the appropriate biological safety containment levels in consultation with the Biosafety Officer (BSO).
- Ensuring strict adherence to biological safety practices and techniques for all work involving potentially biohazardous materials.
- Securing an IBC protocol for the potentially biohazardous materials prior to initiation of any activities.
- Ensuring that personnel are appropriately trained on the potential hazards and precautionary measures applicable to the biohazardous materials, including instruction in specific practices and techniques required for safe handling of the biohazardous materials.
- Non-retaliation against any person reporting real or perceived problems or violations of procedures to supervisors, the ORC, or members of the IBC.

## ***Laboratory Workers***

Anyone who works in a laboratory in a technical capacity is defined as a laboratory worker, whether the person is a faculty member, student, intern, visiting scholar, or volunteer.

Individuals must adhere to biological safety practices and techniques. This includes working with potentially biohazardous material with the appropriate containment and personal protective equipment (PPE) as directed by the supervisor and PI.

Laboratory workers are the most critical element in maintaining a safe working environment.

Each person is responsible for his/her own safety and that of co-workers. Adherence to the MSU and laboratory-specific biosafety practices and procedures in the conduct of laboratory duties, is essential to maintain a safe working environment.

The laboratory worker's responsibilities include:

- Obtaining required training (i.e., Biosafety, rDNA, BBP) prior to the initiation of laboratory work.
- Reading the IBC protocol, emergency and experimental SOPs described in the laboratory-specific biosafety manual.
- Following laboratory-specific biosafety practices and procedures.
- Informing the PI or MSU's Occupational Health Manager of any health condition that may be a result of working in the lab.
- Reporting to the PI or the lab supervisor all problems, procedural discrepancies, spills, or accidental releases as soon as they occur.
- Reporting to the ORC any noncompliance in the biosafety policies, practices, or procedures.
- Non-retaliation against any person reporting real or perceived problems or noncompliance of procedures to supervisors, the PI, the ORC, or members of the IBC.

### ***Institutional Biosafety Committee (IBC)***

The IBC is responsible for reviewing and approving research and teaching activities conducted by faculty, staff, students, and/or visiting scientists on MSU property, and/or under the control of MSU faculty, staff or students, that involve the use of biohazardous materials including regulated animal and plant pathogens, biological toxins, and recombinant or synthetic nucleic acid molecules (see pp.6-7).

The IBC is responsible for the:

- Review and approval of the research or teaching activity performed by individual researchers, on a regular and continuing basis.
- Independent assessment of the containment levels required for the work, as stipulated by the NIH Guidelines and/or BMBL, for all experiments, including those involving whole plants and/or animals, cell cultures, tissues, human-derived materials, biological toxins, infectious agents, and regulated pathogens and pests.
- Assessment of facilities, procedures, practices, and training and expertise of personnel involved with biohazardous research.

- Notification of Principal Investigators (PIs) of the results of the IBC's review and approval.
- Developing emergency plans covering accidental spills and personnel contamination resulting from research using recombinant or synthetic nucleic acid molecules.
- Reporting of significant problems with, or violations of the NIH Guidelines and any significant research related accidents or illnesses to ORC and the appropriate institutional official, and when necessary to the NIH.
- Suspension or termination of research that is not being conducted in accordance with IBC requirements.

### ***Biosafety Officer (BSO)***

The BSO is responsible for developing, leading, directing, and managing a comprehensive biological safety program at MSU. The biological safety program must meet the requirements of the NIH, CDC, USDA, OSHA, and any other granting agency, as well as federal, state, and local regulations. The program includes close cooperation and interaction with committees approving research protocols and procedures including the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and the Radiation Safety Committee (RSC). The BSO provides guidance and consultation to assess the risk of working with potentially biohazardous materials. The BSO interacts with the MSU research, teaching, and diagnostic community to inform and ensure compliance with state and federal reporting or audit requirements, and to regularly inspect and correct laboratory and worker deficiencies when noted.

The Biosafety Officer:

- Coordinates and approves biocontainment laboratories prior to the initiation of any research related activities.
- Inspects all biosafety laboratories at least on an annual basis, with a focus on
  - The physical biocontainment labs and equipment for compliance with general CDC guidelines on Biosafety Level (BSL) and Animal Biosafety Level (ABSL), using developed laboratory inspection checklists.
  - Laboratory-specific biosafety manuals and standard operating procedures (SOPs) for compliance with guidelines for BSL and ABSL operations.
  - Providing general guidance about health and safety standards, biosafety practices, and biosecurity measures.
  - Proper transport and disposal of biohazards, sharps, and glass waste outside of lab buildings in accordance with applicable state and federal regulations.

- Develops SOPs for dealing with emergency spills of biohazards and rDNA materials.
- Advises PIs in preparation of research proposals and other activities involving biological materials.
- Maintains a list of approved biosafety laboratories with review dates and results.
- Assists the IBC by reviewing all research proposals prior to meetings and provides technical advice on research safety procedures.
- Reports any significant problems, compliance issues, or research-related accidents or illnesses to the IBC.

### ***IBC Program Manager***

The MSU IBC Program Manager coordinates and manages the institutional review and approval process of proposed research activities involving biological materials.

The IBC Program Manager responsibilities include:

- Organization and implementation of the administrative procedures related to the biosafety protocol process.
- Communication and follow up of committee requests to PIs, to secure approval.
- Preparation of correspondence, reports, agendas, minutes, and IBC approval letters.
- Maintaining all records related to IBC activities.
- Organization, and dissemination of materials in advance of each IBC meeting.
- Managing committee processes, organizing meetings, and recording of IBC meeting minutes.
- Facilitating the IBC protocol submission, review, and approval process.

### ***Safety and Risk Management***

Safety and Risk Management (SRM) supports research and other activities involving general laboratory safety, public health, and occupational health. In addition, SRM maintains programs and educational materials pertaining to laboratory safety and the bloodborne pathogen standard medical surveillance program.

# Authority of the IBC

## ***Scope of authority***

The IBC has authority to approve, require modifications, or withhold approval on all research, teaching, or diagnostic activities that fall within its jurisdiction as specified by both the federal regulations and MSU Institutional Policy (see pp.6-7). For activities that do not require an IBC protocol (e.g. teaching lab programs that use only RG1/BSL1 bioagents), the instructor or lab manager may consult the IBC for guidance. In this capacity, the IBC may advise and “endorse” teaching lab biosafety practices.

## ***Approve, return for modification to secure approval, withhold approval, or suspend.***

The IBC approves protocols for three years. Prior to the expiration date, a new IBC protocol must be approved if the research activities are to continue. If the new protocol is not approved by the expiration date, the BSO and IBC Chair will exercise their professional judgment to determine whether to grant an extension of the deadline, or to suspend research activities.

The IBC functions independently of other committees and bases its decisions on protocol approvals as to how thoroughly the protocol’s biosafety aspects adhere to relevant regulations, guidelines, and policies with the goal to ensure a safe and compliant working environment. The IBC has jurisdiction over all research involving regulated or potentially biohazardous materials, thereby providing broader protection than required by the regulations.

## ***Annual Renewals***

Any approved research or protocol is subject to continuing IBC review and is evaluated annually.

## ***Review of Amendments***

All modifications to approved research/activities are required to have IBC review and approval prior to implementation. Amendments are submitted electronically.

An amendment may require full IBC review if the changes to the protocol are significant. Examples of significant changes include the addition of potentially biohazardous materials,

and the addition of materials or procedures that may increase the risks of the research.

Minor amendments may be approved administratively by the IBC Chair or the BSO.

Examples of administrative amendments may include:

- 1) A change in research personnel, i.e. the addition of new, or the omission of departing laboratory personnel on the protocol.
- 2) A change of laboratory venue, if change is to an equivalent and approved facility, and the BSO certifies the venue through the inspection process.
- 3) Based on the discretion of the BSO, addition of biohazardous materials such as microorganisms or cell lines that are equivalent in Risk Group (RG) and biosafety containment level (BSL) to the biological agents listed on the protocol.

Examples listed above are not comprehensive. The IBC Chair in conjunction with the BSO may utilize professional judgement to determine if a modification is suitable for administrative approval.

### ***Suspension or termination of approved projects***

The IBC has the authority to suspend or terminate approval of research that is not conducted in accordance with the IBC's requirements or associated with unanticipated or adverse events. Any suspension or termination of approval shall include rationale for the IBC's action and shall be reported promptly to the PI and the IO.

# IBC Membership

## ***Committee Size***

The IBC will have no less than five members with varying backgrounds to review research, teaching, and diagnostic activities involving biohazardous materials and rDNA conducted at MSU.

## ***Qualification***

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.

## ***Representation***

The IBC will be sufficiently qualified through member experience and expertise to promote respect for its advice and capability to assess the safety of research, teaching, and diagnostic activities and to identify any potential risk to worker, public health, or the environment.

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

The BSO will be a voting member.

At least one member whose primary expertise is in plants, and one member with expertise in animals and animal containment principles will be appointed to the IBC.

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

# Management of the IBC

## IBC Chair

### ***Appointment***

The Chair is appointed by the IO. The Chair serves for at least one year and may be reappointed.

If the Chair is unavailable for a scheduled meeting, the Vice-Chair or a committee member chosen by the IO, will serve as a substitute IBC Chair.

### ***Duties***

The Chair directs the IBC meetings in accordance with institutional, state, and federal requirements. The Chair works closely with IBC members, the IO, the IBC Program Manager, the BSO, and PIs to ensure that research and other activities involving regulated or potentially biohazardous materials are conducted safely and in accordance with all regulations, policies, and procedures. The Chair is the designated signatory for the IBC and conducts all IBC meetings. The IBC Chair responsibilities include:

- Presiding over the committee to review the institution's program for the safe conduct of all research and teaching activities by faculty, staff, and students that utilizes infectious agents, human body fluids or tissues, and recombinant or synthetic nucleic acid molecules (see pp.6-7).
- Assisting in the selection of voting members.
- Assigning primary reviewers to the protocols.
- Managing the monthly IBC meeting.
- Clarifying the committee's potentially complex decision with the Principal Investigator.
- Participating in laboratory inspections.
- Serving on subcommittees for modifications requiring secondary votes and beyond.
- Working in cooperation and interacting regularly with the IBC Program Manager to ensure smooth functioning of the committee.

The Chair and BSO are authorized to approve electronic Proposal Clearance Forms (ePCF). The Chair counts toward a quorum at meetings and is a voting member.

### ***Removal***

The Chair may be removed or replaced by the IO.

## **IBC members**

### ***Selection and Appointment***

Members are appointed by the IO based upon the recommendation of the IBC Chair.

### ***Duties***

IBC members are responsible for ensuring that all research and other activities utilizing regulated or potentially biohazardous materials are reviewed and approved in a manner consistent with federal regulations, guidelines and institutional policy.

### ***Removal***

IBC members may be removed or replaced by the IO.

## ***IBC Training***

### ***Orientation***

When a new member or Chair is appointed to the IBC, the BSO and IBC Chair will hold a New Member Orientation. This orientation will introduce these new members to the federal regulations, MSU IBC meeting procedures, review process, and the IBC forms.

### ***Continuing Education***

Continuing education of IBC members is done through periodic training sessions, as well as educational information distributed to members. In addition, the IBC Program Manager, BSO, IO, IBC Chair, and other committee members may attend professional development conferences throughout the year to keep current on emerging biosafety issues and best practices.

### ***Reference Materials***

The [MSU IBC Manual](#), and other specific MSU policies and procedures are accessible on the MSU Biosafety website. The federal regulations and guidelines can be found online as well: the [BMBL](#) (Biosafety in Microbiological and Biomedical Laboratories, 2009 5th Ed.), the [NIH](#)

[Guidelines](#) for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2016), and the OSHA Bloodborne Pathogen Standard [1910.1030](#).

### ***Use of Consultants***

The IBC may utilize non-member consultants for advice and information in specialized areas as needed. These consultants may be MSU faculty or staff or may be unaffiliated with MSU. The consultants may present their assessments in writing or in person. Consultants are not allowed to vote on the disposition of protocols.

## **Conflict of Interest Policy**

### ***Recusing of Voting Members***

Review of protocols/modifications will be conducted with objectivity and in a manner to the 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 research role or have an actual, perceived or potential conflict of interest. The IBC member must make any conflict of interest known to the IBC Chair. The fact that a protocol is submitted by another investigator from an IBC member's department does not, in and of itself, constitute a conflict of interest. Members that have a potential conflict of interest will be required to recuse themselves from the meeting room during voting. Failure to abide by these provisions may be cause for removal of a member from the IBC.

# Operation of the IBC

## ***Scheduling of meetings***

The 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 Program Manager. IBC meetings are open to the public and meeting dates for the current year are posted on the IBC webpage.

## ***Pre-meeting distribution of the IBC review materials to members***

Committee members will be provided with the following IBC materials prior to the meeting:

1. Meeting agenda
2. Minutes from the previous meeting
3. Protocols and modifications to be reviewed
4. New business

## ***The Review Process***

The IBC is responsible for the review and approval of all projects involving potentially biohazardous materials conducted at MSU regardless of the funding source. The IBC will consider all information presented in the IBC protocol/modification. The IBC may request additional information and/or clarification from the PI.

Review of submitted protocols:

- Pre-Review – The BSO will conduct a Biosafety Pre-review of all submitted protocols and may contact the investigator with additional questions that arise as part of this review process.
- Committee Review – The BSO will assign a committee member(s) as a primary reviewer(s). Primary reviewer(s) will review the protocol clarify any questions, discrepancies, or concerns with the PI prior to the IBC meeting. Alternatively, the reviewer may ask the BSO or Chair to contact the PI on his/her behalf.
- All committee members are expected to review each protocols and modifications.
- Each protocol will be discussed at convened meetings.

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

- I. **Approve:** The IBC may make a motion and vote to approve the protocol as submitted.
- II. **Return for Modification:** If additional information or clarification is required to secure approval, the IBC Program Manager will communicate the items from the committee to the PI. Response to items is evaluated by a subcommittee. If the subcommittee votes unanimously that the concerns were adequately addressed, the protocol is approved. If the subcommittee does not vote unanimously for approval, the protocol is returned for modification and the PI must resubmit the protocol for full committee consideration.
- III. **Withhold approval:** If a majority of the IBC believes that the proposed research activities are too hazardous, the proper expertise or facilities are not available, or the protocol lacks sufficient details, the protocol will be disapproved. In such cases, the IBC will provide feedback to the PI and make recommendations regarding potential resubmission.

The IBC Program Manager 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.

## ***Voting requirements***

### ***Quorum required***

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

### ***Full voting rights of all reviewing members***

Each member has one vote.

### ***No proxy votes***

No proxy votes are allowed.

### ***Prohibition of conflict-of-interest voting***

IBC members will 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.

## ***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 in writing by the IBC Program Manager.

## **IBC Record Keeping Requirements**

### ***IBC membership roster***

Each year the IBC Program Manager will submit the membership roster and curriculum vitae demonstrating the qualifications of each committee member to the National Institutes of Health Office of Biotechnology Activities (NIH-OBA).

### ***Written procedures and guidelines***

Written IBC procedures and guidelines are contained in the IBC manual.

### ***Minutes of meetings***

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

1. Members present
2. Others present
3. Summary of discussions
4. Motions made and seconded
5. Record of voting
6. Assurances that the current OBA Guidelines are adhered to:
  - a. Per February 23, 2007 Guidelines
    - i. IBC determines the appropriate containment per NIH Guidelines.
    - ii. IBC assures that facilities, procedures, practices, training and expertise of personnel involved in rDNA research are appropriate.
    - iii. IBC periodically reviews recombinant DNA research to ensure compliance with the NIH guidelines.
  - b. IBC Minutes must include
    - i. Agent characteristics (e.g. virulence, pathogenicity, environmental stability)
    - ii. Types of manipulations planned

- iii. Sources of the inserted DNA sequences
- iv. Nature of the inserted DNA sequences
- v. Hosts and vectors to be used
- vi. Whether an attempt will be made to obtain expression of a foreign gene and if so the protein that will be produced
- vii. Containment conditions to be implemented
- viii. Applicable section of the NIH Guidelines

### ***Retention of records***

All reviewed protocols and related materials will remain on file at ORC for three years after the completion of the research. The IBC maintains a database of all proposed and active projects and activities involving rDNA and biohazardous materials.

Meeting minutes and IBC rosters will remain on file at ORC as a record of the committee's activities.

### **Communication to and from the IBC**

Any questions regarding IBC protocol submission or review should be directed to the IBC Program Manager.

The IBC Program Manager keeps in contact with researchers regarding IBC decisions and requests for additional information.

## PI Responsibilities

### ***IBC protocol***

A Principal Investigator (PI) applying for IBC approval for research, teaching, or diagnostic activities needs to submit a completed IBC protocol. For the application to be processed, it must be signed (electronically) by the PI and any supplemental materials must be included.

A PI applying for approval of teaching activities involving potentially biohazardous material (pp.6-7) must contact the BSO. The BSO will assist the PI in developing appropriate biosafety training for students. The PI is responsible for ensuring that all students are trained prior to working with the agents. The BSO will act as a resource to assist the PI in developing a Biosafety Manual and performing a facility review.

The IBC protocol form is available via the [IBCOP webpage](#).

### ***IBC amendments***

All amendments to currently approved research and diagnostics activities are required to have IBC review and approval prior to implementation. Minor changes may be processed as an administrative approval performed by the IBC Chair and/or BSO.

Examples of significant amendments may include the addition of potentially biohazardous materials, and the addition of materials or procedures that may increase the risks of the research.

Administrative modifications may be approved by the IBC Chair or the BSO as described previously.

The IBC amendment approval is valid until the end of the original approval period (3 years).

### ***Reports of unanticipated adverse events***

All unanticipated/adverse events must be reported to the BSO and IBC Chair. NIH Guidelines require that the PI report any significant events to IBC representatives and OBA within 30 days.

### ***Notification***

Approximately, 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. PIs desiring to continue their research are responsible for completing a new IBC protocol and returning it to the IBC Program Manager in time for review at the IBC meeting prior to the expiration date.

Approximately one month prior to the expiration date, a second notification will be emailed. If the PI doesn't respond at the end of the third month the last notification will indicate that the protocol is expired. The PI will be notified in writing of this expiration and at this time all work on this project must be finished/discontinued.

# **Biosafety Laboratories:**

## **Inspections, manuals, OSHA BBP Exposure Control Plan**

### ***Biosafety laboratory inspections***

The BSO periodically inspects Biosafety labs (BSL-1, 2, and 3, ABSL-1, 2 and 3) utilizing a [checklist](#) and reporting results to the IBC.

### ***Biosafety manuals***

The BSO works with the PI to review [Laboratory-Specific Biosafety Manuals](#). The IBC considers the status of the lab-specific biosafety manual when reviewing and approving protocols. This biosafety manual is reviewed by the BSO during laboratory inspections or as needed. PIs are encouraged to make sure that all research personnel read and understand the [MSU Biosafety Manual](#).

### ***OSHA Bloodborne Pathogens Standard and OSHA BBP Exposure Control Plan***

MSU's Occupational Health Manager and the BSO are responsible for assisting the PI in adhering to the [OSHA Bloodborne Pathogen \(BBP\) Standard](#). Guidance and experimental application are provided to researchers in the [MSU BBP Exposure Control Plan](#).

### ***Teaching Activities***

Guidance to laboratory Instructors is provided in the [MSU Biosafety Manual](#) and through consultations with the BSO. In addition, the BSO will perform inspections of all BSL1 and BSL2 teaching laboratories, on an annual basis or as needed. During BSO consultations or inspections, the Instructor may be informed that an IBC Teaching protocol is required, based on the type(s) of activities occurring in the classroom. See pp. 6-7 of this manual for a list of activities that require IBC approval.

## Materials and Activities Requiring Permits or Approvals

Many biological materials and activities require additional federal permits. Any biological material that requires a federal permit should be registered with an IBC protocol.

### ***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](#).

### ***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 etiologic agents. Additional information can be found at the [CDC website](#).

### ***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 the BSO or other environmental safety officer.

### ***Field trials of genetically modified organisms***

Field trials of genetically modified organisms always require permits from APHIS. Additional requirements may be needed if the proposed field trials include transgenic plants expressing molecules of pharmaceutical intent. There are specific regulations and requirements for the “Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds” ([7 CFR Part 340](#)).

## Bloodborne Pathogens

Activities utilizing human and primate tissues, cells, blood and other potentially infectious materials must comply with federal and state requirements. These materials are always considered to be potentially infectious agents and must be treated as pathogens.

### ***Activities that deal exclusively with agents covered under the [OSHA BBP standard](#)***

For this work to comply, the PI will work with SRM and ORC to implement the [MSU BBP Exposure Control Plan](#) (ECP).

### ***Bloodborne pathogens program and training***

Bloodborne pathogen program and training is administered by SRM and ORC.

### ***Biosafety level***

Research activities with blood and other body fluids must be performed using BSL2 practices.

### ***Human cell lines***

Requirements for working with unfixed human cell lines are based upon whether the tissue is a primary explant, or a cell line derived from primary explants (typically those collected by a researcher or a colleague) or established, transformed human cell 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.

### ***Primary Human and NHP Cells/Tissues/Established Human and NHP Cell Lines***

Work with primary human or NHP cell lines requires adherence to the MSU Bloodborne Pathogen Program. Established or transformed cell lines (such as those obtained from the ATCC) may not be pathogen free (e.g. accidentally contaminated with laboratory pathogens). Work with these cells, tissues or cell lines requires:

- Registration with the IBC via an IBC protocol
- Performance of the work in a BSL2 laboratory facility following BSL2 practices.
- Implementation of [MSU BBP Exposure Control Plan](#).
- Bloodborne pathogen and biosafety training.
- Individuals working with human cell lines must be offered the hepatitis B immunization.

## **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 authorized individuals to fulfill their job duties.

PIs should identify the risk that a material may pose 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.

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