Institutional Biosafety Committee Manual

Contents

Updates During Review

August 2021

- General updates for consistency, clarification, and grammar/typos
- Page 6: Updated 7 CFR Part 340 Title per eCFR web site
    - Split APHIS permit regulations/guidelines to own line with link to APHIS website
- Page 7: Split Laboratory Supervisors into own section for Duties and Responsibilities (no longer with PI)
- Page 9: add respiratory protection program to SRM Duties and Responsibilities
- Page 10: Update expiration date language – last day of the month in which protocols are approved
    - Interim Reviews: add language about inactivation if not approved by review date and language about reviews being approved by BSO
- Page 18: Add notification language for Interim Reviews and update timing of emails for both reviews and renewals/submission due dates

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 or synthetic nucleic acid molecules (e.g., 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 (SOPs; e.g., emergency procedures, experimental methods), and administrative controls (e.g., training, occupational health, lab inspections) 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, fungi, prions, rickettsia, and viruses), toxins, and recombinant/synthetic nucleic acid materials 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, cell cultures, soils, and infected plants are also considered biohazardous.

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

- Recombinant or synthetic nucleic acid molecules (e.g., 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 regulated genetically modified organisms to be introduced into the environment.
    - 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).
  Note: the possession, use, or transfer of Select Agents and Toxins entails additional requirements – contact the ORC for additional information.
- Unfixed human and non-human primate cells (including cell lines), tissue, blood, and potentially infectious body fluids.
- Toxins of biological origin.
- 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.

Principles Which Govern the IBC

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

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).
- Biosafety in Microbiological and Biomedical Laboratories (BMBL).
- 7 CFR Part 340, Movement of Organisms Modified or Produced Through Genetic Engineering
- APHIS Permit regulations/guidelines.
- 42 CFR Part 73, Select Agents and Toxins
- 7 CFR Part 331 and 9 CFR Part 121, Possession, Use, and Transfer of Select Agents and
- 29 CFR 1910.1030 Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens

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/synthetic nucleic acid molecules 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

Principal Investigators (PI) are responsible for the conduct of people and activities in their laboratories. PIs 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 with the assistance of the Biosafety Officer (BSO).
- Development of biosafety plans and SOPs for all applicable activities.
- Establishment of the appropriate biological safety containment levels in consultation with the 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 Supervisors

Laboratory Supervisors/Managers are responsible for assisting the PI with the above responsibilities.

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 PI and Supervisor. 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 (e.g., OSHA Bloodborne Pathogens) 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.

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.
- Notifying the Principal Investigators 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), Animal Biosafety Level (ABSL), and Plant Biosafety Level (BSL-P), using developed laboratory inspection checklists.
    - Laboratory-specific biosafety manuals and standard operating procedures (SOPs) for compliance with guidelines for BSL, ABSL, and BL-P 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 recombinant/synthetic 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, IBC meeting minutes, and IBC approval letters.
- Maintaining all records related to IBC activities.
- Organization, and dissemination of materials in advance of each IBC meeting.
- 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. SRM maintains programs and educational materials pertaining to laboratory safety, respiratory protection, 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. 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, Withhold Approval, or Suspend

The IBC approves protocols for three years. Expiration dates are set to the last date of the month approval is granted (e.g., a protocol approved by the committee on October 15th would be given an October 31st expiration date). Prior to the expiration date, a renewal IBC protocol must be approved if the research activities are to continue. If the renewal 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.

Interim Review

An Interim Review protocol is submitted annually following initial approval and again annually after approval of renewal protocols. Interim Review protocols that are not approved by the review date will be suspended and work outlined in the protocol must be stopped until an Interim Review has been approved. During review, amending changes to the original protocol can be made. Interim Review protocols are approved by the BSO unless amendments required further review by the committee. See below for amendment reviews.

Review of Amendments

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

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 by the IBC Chair or the BSO Designated Member Review (DMR).

Examples of Chair/BSO DMR amendments may include:

- A change in research personnel, i.e., the addition of new, or the removal of departing laboratory personnel on the protocol.
- A change of laboratory venue, if change is to an equivalent and approved facility, and the BSO certifies the venue through the inspection process.

- 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.
- 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 Designated Member Review.
- Working in cooperation and interacting regularly with the IBC Program Manager to ensure smooth functioning of the committee.

The Chair, BSO, and IBC Program Manager 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), the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, and the OSHA Bloodborne Pathogen Standard.

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.

Operations 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

The IBC Program Manager will provide 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

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/amendment. 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 IBC Chair will assign a committee member(s) as a primary reviewer(s). Primary reviewer(s) will review the protocol and clarify any questions, discrepancies, or concerns by tagging comments in the protocol. Questions, discrepancies, or concerns should be tagged 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. All committee members have the ability to tag comments in the protocol during the review process.
- 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. There are two options for approval after a return for modification:
    - Return for Modification and Approve by Subcommittee Designated Member Review (DMR): Responses to committee comments are returned and voted upon 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.
    - Return for Modification and Approve by BSO DMR: Minor modifications such as updating personnel training or equipment certification dates may be approved by the BSO upon resubmission.
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

The following are required for IBC voting:

- 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

The IBC provides communication to the investigators 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 or BSO 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 NIH Guidelines
        i. IBC determines the appropriate containment per NIH Guidelines
        ii. IBC assures that facilities, procedures, practices, training, and expertise of personnel involved in recombinant/synthetic nucleic acid molecule research are appropriate.
        iii. IBC periodically reviews recombinant/synthetic nucleic acid molecules 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 nucleic acid sequences
        iv. Nature of the inserted nucleic acid 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 recombinant/synthetic nucleic acid molecules 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 Original Protocol

A Principal Investigator (PI) applying for IBC approval for research, teaching, or diagnostic activities needs to submit a completed IBC protocol. Protocols may be submitted by the PI or their designated lab manager (aka Co-Investigator).

A PI applying for approval of teaching activities involving potentially biohazardous material 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 IBC Webpage.

IBC amendments

All amendments to currently approved research and diagnostics activities are required to have IBC review and approval prior to implementation.

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.

Minor amendments 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).

Interim Review

An Interim Review protocol is submitted annually following initial approval and again annually after approval of renewal protocols. During review amending changes may be made to the original protocol, if desired.

Renewal

A Renewal Protocol is submitted every three years following initial approval of the Original Protocol. Renewal protocols are sent to full committee review. During renewal amending changes may be made to the protocol.

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 of Due Dates

Interim Review

Approximately, three months prior to the due date for an Interim Review, the PI will receive an e-mail notifying them that their approved protocol is due for review. PIs desiring to continue their research are responsible for completing an Interim Review protocol and returning it to the IBC Program Manager in time for review at the IBC meeting prior to the expiration date. Protocols must be submitted thirty days prior to the IBC meeting prior to the protocol's review date.

Approximately two months prior to the review date, a second notification will be emailed. If the PI doesn't submit an Interim Review protocol by the due date, the last notification will indicate that the protocol has been inactivated. The PI will be notified in writing of this and at this time all work on this project must be finished/discontinued.

Expiration

Approximately, three 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 renewal protocol and returning it to the IBC Program Manager in time for review at the IBC meeting prior to the expiration date. Protocols must be submitted thirty days prior to the IBC meeting prior to the protocol's expiration.

Approximately two months prior to the expiration date, a second notification will be emailed. If the PI doesn't submit a Renewal protocol by the due date, 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.

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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