Montana State University-Bozeman

Institutional Biosafety Committee Manual

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Certification and Approvals

Signature of IBC Chair **Date**

Mike Babcock

Print Name

Signature of Director of Research Compliance **Date**

Justin Cook

Print Name

Signature of Biosafety Officer **Date**

Kirk Lubick

Print Name

Previous Review Dates

Institutional Biosafety Committee

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 at MSU. 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 and other activities submitted.

Purpose of the IBC

The IBC oversees and establishes MSU policy for review and approval of all activities involving the use of recombinant DNA and potentially biohazardous materials to assure compliance with current regulations and guidelines. Principal Investigators (PI) and/or laboratory supervisors at MSU who either store or carry out research or diagnostic activities involving potentially biohazardous materials must inform the IBC via an IBC protocol.

It is the policy of MSU that all activities involving potential biohazardous material be conducted in a safe manner in order to protect laboratory workers, students, our community, and the environment from potentially biohazardous agents and in such a manner that projects conducted by one faculty member will not have an adverse effect on adjacent projects conducted by other scientists. The Office of Research Compliance (ORC) will maintain all related records for 3 years after the completion of the research activity.

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

Research and Activity Requiring Review and Approval from the IBC

The IBC reviews and approves many areas of biologically related activities which may include: research, teaching, and diagnostic activities.

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

Potentially biohazardous materials include, but not limited to, all of the categories below. Projects involving materials included in any of these categories must be submitted for IBC approval prior to initiating the project.

- Recombinant DNA (rDNA)
- Genetically modified organisms. 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 (human, animal, plant, and other).
- 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 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.

Principles which Govern the IBC

The IBC developed this manual and operates based upon 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 Bloodborne Pathogen Standard

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

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

Duties and Responsibilities

Principal Investigators and Laboratory Supervisors

The PI is primarily responsible for the people and activities in their laboratories and are responsible for implementing an appropriate biological safety program specific for their projects.

PI's 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 Biosafety Officer (BSO) and 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 start of any activities involving the use of potentially biohazardous materials, the PI must register the potentially biohazardous materials they propose to use with the IBC. 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

biohazardous materials. This includes instruction in specific practices and techniques required for safely handling the biohazardous materials.

Laboratory Workers

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

Whoever works in the laboratory in a technical 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 their own safety and that of their co-worker. If individuals do not follow the MSU and laboratory-specific biosafety practices and procedures in the conduct of their laboratory duties, MSU cannot maintain a safe working environment. It is the laboratory worker's responsibility to:

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

Institutional Biosafety Committee

The IBC is responsible for reviewing and approving practices and protocols for the handling of rDNA and potentially biohazardous materials at all research facilities at MSU. The IBC is comprised of faculty representatives, from various academic disciplines, researchers, non-scientific members, students, and community representatives who are not affiliated with MSU. The Committee typically meets monthly to review research and other activities submitted to the committee.

Biosafety Officer

The BSO is responsible for developing, leading, directing, and managing a comprehensive biological safety program for MSU. The biological safety program must meet NIH, CDC, USDA, OSHA, any other granting agency, Federal, State, and local requirements. The program includes close cooperation and interaction with committees approving research protocols and procedures for use of human subjects (Institutional Review Board (IRB)), Institutional Animal Care and Use Committee (IACUC), and Radiation Safety Committee (RSC). The BSO will provide 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 effect actions to inspect and correct deficiencies when noted.

The BSO coordinates and approves facility reviews. All biosafety laboratories are inspected on an annual basis. These inspections involve:

- The inspection of the physical facilities and containment equipment for compliance with general CDC guidelines for Biosafety Level (BSL) and Animal Biosafety Level (ABSL) laboratories for research and diagnostic work using developed laboratory inspection checklists.
- 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 provides the biosafety review for all research proposals presented to the IBC.
- 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 review dates and results.

The BSO is responsible for assisting the PI to develop appropriate Biosafety Manuals for all activities using potentially biohazardous materials.

IBC Coordinator

The MSU IBC has an IBC Coordinator to manage the confidential institutional review and approval process of proposed research activities involving biological materials. The IBC Coordinator is responsible for the following:

- Communicates committee requests to investigators for additional information and revisions and reviews investigator 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 Director of Research Compliance (Institutional Offcial (IO)) as needed).
- Facilitates committee approval for emergency or unique opportunity situations.
- Advises principal investigators in preparation of applications for research proposals and other activities involving biological materials.
- Maintains all records related to IBC activities.

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 disapprove all research, teaching, or diagnostic activities that fall within its jurisdiction as specified by both the Federal Regulations and MSU Institutional policy.

Approve, modify, or disapprove projects

The IBC approves protocols for up to three years. After three years the IBC protocol must be resubmitted if the research continues. The IBC 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 IBC has jurisdiction over all research involving regulated or potentially biohazardous materials, thereby providing broader protection than required by the regulations.

Progress reports from investigators

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

Approve/disapprove modifications

All modifications to currently approved research/activities are required to have IBC review and approval prior to implementation. Modifications are submitted on an IBC modification form.

A modification may require full IBC review if the modification is significant. Examples of significant modifications 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. Examples of administrative modifications may include the addition of personnel, and change of laboratory room (if change is to an equivalent and approved facility). The IBC modification is only good until the end of the original approval period.

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 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 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 the experience, 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.

As appropriate, 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 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 IO may appoint a temporary Chair.

Duties

The Chair directs the IBC meetings in accordance with Institutional and Federal requirements. The Chair works closely with IBC members, the IO, the IBC coordinator, the BSO, 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 and BSO are authorized to approve Electronic Proposal Clearance forms.

The Chair counts towards 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. MSU faculty members appointed to the IBC will serve on the board for a one year term.

At the conclusion of their terms a committee member may be appointed to an additional term and/or year of service. There is no limit to the number of terms a member may serve on the IBC.

Duties

MSU 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 specially scheduled trainings, as well as educational information distributed to members through newsletters or by discussing them at a full committee meeting. At a minimum, this training will occur once a year. The IBC Coordinator, BSO, IBC chair may attend professional development conferences throughout the year to keep current on IBC issues.

Reference Materials

Each IBC member is provided with the URL of the MSU IBC Manual which includes the specific MSU policies and Procedures.

Use of Consultants

The MSU IBC is encouraged to use 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

Reviews of applications 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 conflict of interest. The IBC member must make any conflict of interest known to

the IBC chair. The member may also be required to provide this information to the IBC if requested. 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.

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Operation of the IBC

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 year are posted on the IBC webpage.

Pre-meeting distribution of the IBC review materials to members

Seven calendar days prior to a monthly meeting the IBC coordinator will send to each committee member the following IBC materials:

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 form. The IBC may request additional information and/or clarification from the PI.

Review

- Pre-review – Upon receipt of a protocol, the IBC coordinator will pre-review the protocol for completion. The coordinator will contact the investigator if any additional materials are required.
- Tertiary Review – The BSO acts as a tertiary reviewer 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 and/or BSO will assign committee members as primary reviewers. Primary reviewers will carefully review each protocol assigned and clarify any questions/discrepancies/concerns with the PI prior to the scheduled IBC meeting. Alternatively the reviewer may ask the BSO or Chair to contact the PI on their behalf. This approach can be used in cases where the IBC member reviewing the protocol wishes to remain anonymous to the investigator.
- 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. Approve: The IBC may make a motion and vote to approve the protocol as submitted.
  II. Approve pending clarification and review by subcommittee. This type of approval is provided when additional information or requirements must be met prior to approval. The IBC coordinator will communicate the items and concerns from the committee to the PI. The response will be evaluated by a subcommittee consisting of the primary reviewer, IBC chair and BSO. If the subcommittee votes unanimously (3-0) that the concerns were adequately addressed, the protocol is approved. If the subcommittee does not vote unanimously for approval, the protocol is withheld and the PI will need to resubmit the protocol for full committee consideration. If the PI fails to respond to the committee request for additional information prior to the next IBC meeting, the BSO and IBC chair may require resubmission.
  III. Withhold approval: If a majority of the IBC believes that the proposed research activities are too hazardous or the proper expertise or facilities are not available, the protocol will be disapproved. In such cases, the IBC will provide feedback to the PI and make recommendations regarding potential resubmission.

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.

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 coordinator.

IBC Record Keeping Requirements

IBC membership roster

Each year the IBC coordinator will submit the membership roster and curriculum vitae demonstrating the qualifications of each committee member to the NIH-OBA.

Written procedures and guidelines

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

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

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

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

Communication to and from the IBC

The IBC protocol is available from the IBC webpage. Any questions regarding IBC review or the content of the IBC manual should be directed to the IBC coordinator.

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

Information the Investigator Provides to the IBC

IBC protocol

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

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 all 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.

Requests for modifications in activities after approval

All modifications to currently approved research and diagnostics activities are required to have IBC review and approval prior to implementation. Minor changes that do not increase the risk to workers, the community, and/or the environment may be processed as an administrative approval performed by the IBC Chair and/or BSO.

Examples of significant modifications 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. Examples of administrative modifications may include the addition of personnel, and change of laboratory room (if change is to an equivalent and approved facility).

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

Reports of unexpected adverse events

All unanticipated/adverse events should be reported to the BSO and IBC chair in writing as well as any actions taken on the part of the researcher as a response to the adverse event. NIH Guidelines require that the PI report any significant events to IBC representatives and OBA within 30 days.

Notification

Three and 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 coordinator in time for review before the expiration date.

One month prior to the expiration a third 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 and OSHA BBP Exposure Control Plans)

Biosafety laboratory inspections

The BSO inspects Biosafety labs (BSL-1, 2, and 3, ABSL-2 and 3) utilizing checklists and reporting results and recommendations to the IBC. The IBC requires that all BSL-1, 2, and 3 laboratories are inspected annually.

Biosafety manuals

The BSO works with the PI to review biosafety manuals. The IBC considers the status of the laboratory specific biosafety manual when reviewing and approving protocols. The Biosafety Manual is reviewed by the BSO every 3 years.

OSHA Bloodborne Pathogens Standards

MSU's Occupational Health Officer and the BSO are responsible for assisting the PI in adhering to this standard.

Teaching Activities

For teaching activities, the PI/Instructor works with the BSO as a resource to develop student training for the course, the BSO will perform a facility review for BSL-1 and BSL-2 facilities.

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 (http://www.aphis.usda.gov/).

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).

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 IO or the BSO.

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 a pathogen.

Activities whose only exposure to potentially biohazardous material is through work with agents that fall under OSHA BBP standard

For this work to be in compliance, the PI will work with SRM and ORC to implement MSU's 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 should be performed using BSL2 practices.

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.

Primary Human and NHP Cells/Tissues

Work with primary human or NHP cell lines requires adherence to the MSU Bloodborne Pathogen Program. Work with unfixed primary human cell lines requires:

- Registration with the IBC via an IBC protocol
- Work performed in a BSL2 facility following BSL2 practices.
- Implementation of MSU's ECP.
- Bloodborne pathogen training.
- Individuals working with human cell lines should be offered hepatitis B immunization, unless information is available to indicate that hepatitis B is not reasonably expected to be present in the cell line.

Established Human and NHP Cell Lines

Even established or transformed cell lines (such as those obtained from the ATCC) may not be pathogen free (e.g. accidental adulterated with laboratory pathogens). Work with unfixed established human or NHP cell lines requires:

- Work performed following BSL2 practices.
- Some established cell lines must be worked with in a BSL2 facility. The cell line source and BSO should be consulted in establishing the appropriate biosafety level.
- Lab personnel training should include review of the biosafety manual and the ECP.

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 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.

Contact Information

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