



Institutional Biosafety Committee (IBC) Charter

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I. Purview of the Wayne State University IBC

A. Purpose

The Wayne State University (WSU) Institutional Biosafety Committee (IBC) is required by the National Institutes of Health (NIH) as a condition for funding of research that utilizes recombinant DNA or synthetic nucleic acid molecules. Irrespective of an individual’s source of funding, all relevant research performed by WSU Principal Investigators (PI) is subject to the *NIH Guidelines*.

The IBC, in collaboration with the Office of Environmental Health and Safety (OEHS), initiates and promotes safe biological work practices and procedures that serve to establish and maintain a safe and healthy workplace. The IBC exists to aid in the protection of research personnel, human subjects, the general public and the environment.

The IBC advises the Associate Vice President (AVP) for Research Integrity and recommends strategies to guide PIs and the OEHS and enhances WSU’s Biosafety Program. The Biosafety Program provides relevant guidance on the acquisition, use, training, transfer, storage, disposal, and emergency response procedures for promoting good biological safety practices.

For review of protocols, the WSU IBC uses guidance from the *NIH Guidelines for research involving recombinant DNA or synthetic nucleic acid molecules* (2016), MIOSHA Laboratory Safety regulations (general lab safety and bloodborne infectious disease standard), and the Center for Disease Control (CDC).

The *NIH Guidelines* state that “The Institution shall establish an IBC whose responsibilities need not be restricted to recombinant DNA or synthetic nucleic acid molecules”.

As such, the IBC routinely reviews additional research activities, including work with:

1. Microorganisms pathogenic to humans, plants, or animals that require Biosafety Level-2 (or higher) practices and procedures
2. Select agents and select agent toxins
3. Biological toxins with an LD50 \leq 100 ng/kg
4. Cadaveric materials research requiring Institutional Oversight per US Army regulations
5. Inactivated high risk biological organisms or toxins

Note: OEHS (not the IBC) provides oversight on biosafety for research involving human and other non-human primate cells and tissues following CDC recommendations and MIOSHA regulations. This is accomplished through training sessions (Biosafety course, which includes Bloodborne Pathogen training) and Biological Safety Level-2 (BSL-2) lab inspections of WSU owned/ operated laboratories.

B. IBC Authority

The AVP for Research Integrity empowers the WSU IBC to enforce the *NIH Guidelines* and to fully investigate potential violations or compliance problems. Where possible, violations of Federal or State regulations related to research subject to IBC approval will be reviewed at convened IBC meetings and reported to the Office of the AVP for Research Integrity. Violations that require expedited reporting will be reviewed by the Biological Safety Officer, Chair of the IBC, and the AVP. Reporting to the relevant regulatory bodies will be performed by the AVP.

C. IBC Responsibilities

The WSU IBC responsibilities include:

1. Educating PIs on the *NIH Guidelines* and informing them of their responsibilities related to obtaining IBC approval prior to initiating research activities
2. Review and approval of all applicable research



This includes review of:

- Biological risk assessment
 - Proposed containment level
 - Facilities
 - Training and expertise of PI and personnel
3. Notifying the PI of IBC review and approval.
 4. The IBC will not approve experiments that are not explicitly covered by the *NIH Guidelines* until the NIH establishes the containment level.
 5. Periodic review of recombinant DNA and nucleic acid molecules research conducted at WSU to ensure compliance with the *NIH Guidelines*.
 6. Setting containment levels and modifying containment levels (based on risk assessment) for ongoing research activities as warranted.
 7. Consulting with clinical experts to address Occupational Health requirements related to research activities at WSU and covered by the IBC
 8. Implementing contingency plans for handling accidental spills and exposure events resulting from recombinant DNA research.
 9. Investigating potential violations of the *NIH Guidelines*.
 10. Reporting to institutional officials and the NIH Office of Science Policy (OSP) within 30 days any:
 - Significant problems or violations of the *NIH Guidelines*
 - Significant research related accidents or illnesses
 11. Immediate reporting to institutional officials and the NIH OSP of any spills or accidents in BSL-2 facilities that result in an overt exposure
 12. Investigating and reviewing potential violations of other State or Federal regulations
 13. Reporting to institutional officials and relevant regulatory agencies of any significant violations
 14. Reviewing Institutional procedures and practices.
 15. Performing such other functions as may be delegated to the IBC

Note: For gene transfer experiments in human subjects, the WSU IBC defers the review of these protocols to the Western IRB with which WSU has contracted to ensure compliance with all State and Federal regulations, including the *NIH Guidelines*.

II. Principal Investigators Responsibilities

PIs are responsible for knowledge of, and full compliance with, the *NIH Guidelines* and other relevant regulatory agencies.

Prior to initiating research subject to IBC review, the PI must:

- Determine if the research is subject to IBC oversight
 - Consultation with the Biological Safety Officer is available for verification of the PI determination
 - Work deemed to be exempt from the *NIH Guidelines* is not required to be registered with the IBC
- Submit a research protocol to the IBC for review and approval
 - Propose physical and biological containment levels
 - Propose appropriate microbiological practices and laboratory techniques to be used for the research
- Obtain IBC approval
- Obtain approval from other regulatory agencies or Institutional Oversight committees

While conducting research subject to IBC review, the PI must remain in communication with the IBC throughout the duration of the project to:

- Determine the need for IBC review before modifying the approved protocol
- Submit amendments for any changes to the IBC approved protocol prior to implementing the changes for review and approval
- Report any significant problems pertaining to the operation and implementation of containment practices and procedures, violations of the *NIH Guidelines* or other regulatory standards, or any significant research related accidents and illnesses to the Biological Safety Officer

As part of this general responsibility, the PI should:

- Be adequately trained to perform the proposed research activities



- Provide laboratory staff with protocols describing potential biohazards and necessary precautions
- Instruct and train laboratory staff in:
 - The practices and techniques required to ensure safety, and
 - The procedures for dealing with accidents
- Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g. vaccinations or serum collection)
- Supervise laboratory staff to ensure that the required safety practices and techniques are employed
- Correct work errors and conditions that may result in accidental release of recombinant or synthetic nucleic acid molecules or other regulated materials
- Ensure the integrity of physical and/or biological containment
- Comply with permit and shipping requirements for recombinant or synthetic nucleic acid molecules or other regulated materials
- Adhere to IBC approved emergency plans for handling accidental spills and personnel contamination

III. IBC Membership

A. NIH Requirements for IBC Membership

As stated in the *NIH Guidelines* for research involving recombinant or synthetic nucleic acid molecules the IBC shall consist of no fewer than five members that collectively have:

- Experience and expertise in recombinant or synthetic nucleic acid molecule technology
- The capability to assess the safety of recombinant or synthetic nucleic acid molecule research
- The capability to identify and evaluate potential risk to public health or the environment

At least two members of the local community who are not affiliated with WSU (apart from their membership on the IBC) must be members of the IBC and represent the interests of the surrounding community with respect to health and protection of the environment

The IBC must also include at least one member with the following expertise when related research protocols are submitted to the IBC:

- One member must have expertise in animal containment principles when research utilizing rDNA or synthetic nucleic acid molecules involving animals is proposed
- One individual with expertise in plant, plant pathogen, or plant pest containment principles when research utilizing rDNA or synthetic nucleic acid molecules involving plants is proposed
- A designated Biological Safety Officer for research involving rDNA or synthetic nucleic acid molecules at BSL-3/4 or large scale (greater than 10 liters)

B. WSU IBC Membership

In compliance with the *NIH Guidelines*, the WSU IBC consists of:

Thirteen Full Members:

- “Full Members” appointed to the IBC will include:
 - One IBC Chair
 - One IBC Vice Chair
 - Two community members
 - One Biological Safety Officer
 - One OEHS Compliance Specialist
 - One member of the Department of Laboratory Animal Resources (DLAR) veterinarian staff
 - WSU faculty members with sufficient expertise to evaluate the range of research activities typically performed at WSU

Alternate Members:

- Individuals may be appointed to the committee as alternates who serve in place of a specific IBC member or multiple members in their absence
- Alternate members must be discipline-matched and have similar expertise, including the same scientific or non-scientific status



- Alternate members may vote in the absence of the member he/she is assigned to as an alternate. If assigned to multiple members, an alternate may only represent a single vote and only counts once towards quorum
- If both the member and his/her designated alternate member are present at a convened meeting of the IBC, the alternate member may not vote unless they are the primary or secondary reviewer on a specific protocol. In these instances, the alternate member will vote in place of the full member
- Alternate members are encouraged to attend all IBC meetings and contribute to the discussion process

Ad-Hoc Members:

Individuals with specialized knowledge/experience in specific research fields will be invited to serve as ad-hoc members and review protocols that require expertise beyond that included within the current IBC membership. This includes but is not limited to:

- expertise in plant, plant pathogen, or plant pest containment
- expertise in transgenic invertebrates
- expertise in cadaver research
- expertise in research involving human research participants

C. Quorum Requirements

All full members, or in their absence their designated alternate, have voting rights at each IBC meeting. A quorum constitutes more than 50% of the Full Members rostered on the committee. A majority vote is the majority of the quorum of full members, or in their absence their designated alternate, present at the meeting.

D. Conflict of Interest

No member of the IBC may be involved in the review or approval of a project in which they have been, or expect to be engaged, or in which they may have a professional or financial interest, except to provide information requested by the IBC. The IBC member must abstain from voting. The IBC member cannot contribute towards quorum under these circumstances.

E. IBC appointments

The AVP for Research Integrity will serve as an ex-officio member and will not be a voting member of the IBC. The AVP for Research Integrity is responsible for appointing members to the IBC.



- Members will be appointed by the AVP for Research Integrity for three year terms.
- New members will be appointed for an initial one year term, followed by a two year appointment.
- Returning members will be appointed for three years, unless a term of less than three years is agreed upon prior to appointment.
- Members may be re-appointed at the end of each three year term.
- A member who cannot serve a complete term (e.g. sabbatical or separation) may be replaced by a new member who will be expected to serve the remainder of the initial member's term, unless the initial member plans to return and complete his/her term.
- Removal of a member from the IBC typically requires documented and substantiated "just cause" that demonstrates the member to be unfit or unable to serve on the IBC. "Just cause" for removal may include, but is not limited to, lack of participation in IBC related activities (including attendance at meetings, number of reviews completed) a finding of misconduct, or an unresolved conflict of interest. Members may also be removed to allow for fresh perspectives on the committee. The ultimate decision to remove a member is made by the AVP for Research Integrity.

F. IBC Member Training

All newly appointed members are required to complete the CITI training module on the regulatory responsibilities and functions of the IBC. This training must be completed before a new member participates in committee activities (e.g. convened meetings, protocol review and approval, and voting). Refresher training is required of all IBC members when re-signing a new three year term. The CITI training module covers topics that will enhance members' understanding of biosafety-related issues and review policies. The Biological Safety Officer and/or the IBC Chair will facilitate this training.

G. IBC Member Responsibilities

The AVP for Research Integrity shall:

1. Ensure that IBC meets the requirements set forth by the NIH and carries out its required functions
2. Determine the responsibilities of the IBC beyond recombinant or synthetic nucleic acid molecule research



3. Appoint members as described in section E above
4. Ensure appropriate training for the IBC Chair, members, and Biological Safety Officer is available
5. Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents or illnesses to NIH OSP within thirty days; unless the institution determines that a report has already been filed by the PI or IBC

The Biological Safety Officer shall:

1. Serve as the IBC coordinator and understand all functions, policies, and procedures of the IBC and the University's biosafety program
2. Report to the IBC and the AVP of Research Integrity any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses of which the Biological Safety Officer becomes aware
3. By instruction from the AVP, serve as liaison with the NIH and other federal and state regulatory agencies
4. By instruction from the AVP, coordinate with the WSU Department of Marketing and Communications regarding media relations and public disclosures
5. Schedule and attend meetings of the IBC
6. Set meeting agendas and assist the IBC Chair with reviewer assignments
7. Distribute protocols to designated reviewers
8. Review research protocols at convened meetings of the IBC
9. Assist the IBC Chair with the drafting of letters from the IBC regarding IBC decisions and actions
10. Sign IBC letters, as needed
11. Make decisions about researcher responses to IBC conditions for protocol approval, in collaboration with the IBC Chair
12. Assist in the development and implementation of new standard operating procedures (SOPs)
13. Provide advice on laboratory security



14. Assist with periodic reviews of IBC policies and procedures
15. Participate in periodic review of the IBC Charter and update as necessary
16. Develop and complete required biosafety training and provide advice to PIs and the IBC on research safety procedures
17. Perform Biological Safety visits (“Biovisits”) to individual PIs laboratories prior to full approval and report on these visits at scheduled IBC meetings

The IBC Chair shall:

1. Serve as a member of the IBC and understand all functions, policies, and procedures of the IBC and the University’s biosafety program
2. Review and make recommendations on any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses reported by the Biological Safety Officer
3. Attend scheduled meetings of the IBC
4. Direct the proceedings of convened meetings of the IBC
5. Review research protocols at convened meetings of the IBC
6. Assist in setting meeting agendas
7. Designate reviewer assignments
8. Provide written communication regarding IBC decisions to PIs
9. Sign IBC letters, as needed
10. Make decisions about researcher responses to IBC conditions for protocol approval, in collaboration with the Biological Safety Officer
11. Assist in the development and implementation of new Standard Operating Procedures (SOPs)
12. Assist with periodic reviews of IBC policies and procedures
13. Ensure member training (this task may be delegated to the Biological Safety Officer)
14. Participate in periodic reviews of the IBC Charter and update as necessary
15. Complete required biosafety training

The IBC Vice-Chair shall:

1. Serve as a member of the IBC and understand all functions, policies, and procedures of the IBC and the University's biosafety program
2. Review and make recommendations on any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses reported by the Biological Safety Officer
3. Attend scheduled meetings of the IBC
4. Perform duties of the Chair in the Chair's absence or in instances where the Chair has a conflict of interest
5. Participate in periodic review of the IBC Charter and update as necessary
6. Assist with periodic reviews of IBC policies and procedures
7. Complete required biosafety training

WSU IBC members shall:

1. Understand all functions, policies, and procedures of the IBC and the University's biosafety program
2. Review and make recommendations on any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses reported by the Biological Safety Officer
3. Attend scheduled meetings of the IBC
4. Notify the IBC Coordinator when unable to attend IBC meetings
5. Complete required biosafety training
6. Review protocols as requested and provide feedback to the IBC Chair, and/or the Biological Safety Officer
7. Assist with periodic reviews of IBC policies and procedures

IBC Community members shall:

1. Understand all functions, policies, and procedures of the IBC and the University's biosafety program



2. Review and make recommendations on any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses reported by the Biological Safety Officer
3. Attend scheduled meetings of the IBC
4. Notify the IBC Coordinator when unable to attend IBC meetings
5. Complete required IBC training
6. Represent the interests of the surrounding community with respect to health and protection of the environment

H. Meetings

Meetings are held monthly with the schedule being published on WSU OEHS website. Members must be either physically present or connected to the meeting via phone or internet service in order to count towards quorum. IBC meeting minutes are provided to IBC members at the following monthly meeting, and are approved by committee vote. Applicants may attend any IBC meeting or review meeting minutes with prior notification of the IBC Chair.

Upon request, the IBC minutes shall be made available to the public. When possible and consistent with protection of privacy and proprietary interests, meetings are open to the public.

Comments from the public will be recorded in the meeting minutes and either addressed during the course of the meeting, or reviewed and discussed with the relevant institutional representatives.

When warranted, public comments will be reported to the NIH OSP.

IV. Protocol Reviews

A. Approval Procedures of the WSU IBC

Steps for IBC Approval:

- a. IBC approval requires completion of an IBC application in e-Protocol. Submission includes attachment of lab specific biosafety Standard Operating Procedures (SOPs). Template SOPs are made available on-line, along with guidance documents.
- b. All personnel listed on the protocol must have completed required training modules.
- c. In addition to the laboratory safety modules, all PIs must complete the CITI training module entitled *Principal Investigators: NIH Guidelines involving Recombinant or Synthetic Nucleic Acid Molecules - Basic Course*.



- d. Prior to being able to submit the completed documents to the IBC, each protocol must be approved by the applicants Departmental Chair.
- e. Upon receipt, the Biological Safety Officer will complete an initial review of the application for completeness. If the application is complete, it will be accepted and assigned to a meeting date. Applications must be received by the first of each month for inclusion in that months IBC meeting.
- f. The Biological Safety Officer will provide a pre-review of the document and communicate with the PI via the e-Protocol portal. All corrections and recommended changes to the application must be made and returned to the Biological Safety Officer one week prior to the meeting deadline.
- g. The IBC Chair will assign two IBC members to each protocol one week prior to the meeting date. A review outline is provided to assist reviewers with approval criteria.
- h. The IBC may communicate with PIs and applicants directly to clarify details, specify experimental approaches, advise safe practices, or request further information. Additional forms may be requested, including access to IACUC or IRB forms to assure consistency.
- i. The designated primary reviewer presents each protocol to the committee as a whole for discussion. The primary and secondary reviewers are responsible for providing motions on approval, tabling, or denial of approval following completion of IBC deliberations.
- j. Each eligible committee member votes to determine the outcome of the review.
- k. Notification of the outcome of the IBC meeting is sent out to PI's via e-Protocol within 4 days of the completion of the meeting.
- l. A biovisit will typically be completed prior to IBC approval being granted. Biovisits will be conducted in accordance with the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* and the MiOSHA *Bloodborne Infectious Disease Standard*. Final IBC approval is contingent on a satisfactory biosafety lab inspection.

Note: IBC approval is independent of other oversight committees (e.g. IACUC and IRB).

OEHS approval does not equate to IBC approval for the use of biological agents, transgenic animals, recombinant DNA, and select agents.



Expedited reviews of new protocol submissions are not possible. Full committee review is necessary; therefore *all* IBC applications will be handled as described above.

Approval is given for three years unless otherwise indicated in the IBC approval letter.

B. IBC Review Outcomes

The outcome of the IBC review process depends upon the quality of the information provided in the documents submitted. The IBC is required to assess the risk associated with each experimental design.

Potential outcomes:

1. Approval

Full IBC approval is granted when there are no additional biosafety concerns raised by the IBC in addition to those identified by the PI.

2. Conditional Approval

Conditional Approval is granted when committee members raise minor issues associated with the protocol that must be addressed before the protocol is approved. Review of the modified documents is performed administratively by the IBC Chair, the Biological Safety Officer, and any additional IBC members identified during the meeting. In circumstances where either the IBC Chair or Biological Safety Officer is unable to complete the review of the modified documents, the original primary reviewer will be asked to perform this function. Once conditions are deemed to have been met, the protocol can be approved without further review by the full committee.

3. Tabled

A protocol may be tabled for the following (but not limited to) reasons:

- a. Failure to complete all required documents
- b. Poor quality of written documents
- c. Failure to supply sufficient information in order for the IBC members to complete the risk assessment
- d. Identification of potential issues during biovisit

4. Denial of approval



Denial of approval may occur for the following (but not limited to) reasons:

- a. Excessive risk of proposed activities
- b. Inadequate containment facilities (e.g. work involves risk group 3 or 4 organisms)
- c. Excessive health risk due to immune deficiency, or contraindications to required vaccine
- d. Lack of experience associated with proposed research activities
 - i. PI's may be required to provide a curriculum vitae if concerns are raised by the IBC during protocol review
- e. In the event of a protocol being tabled or denied approval, the IBC will work with the PI to address the issues raised and to seek solutions.

Should the PI fail to respond to the requirements of the IBC within 3 months of the meeting in which it was reviewed, the protocol will be removed from the review process and a new application will be required.

C. Biological Safety Visits (Biovisits)

1. IBC Biovisit:

A Biovisit is typically required for full IBC approval. Inspections are conducted by the WSU Biological Safety Officer. Exceptions are made, at the discretion of the Biosafety Officer, if a recent biosafety visit has been performed for the spaces indicated in the protocol.

This visit provides an opportunity for the Biological Safety Officer to:

- Assess the research facilities selected for use in specific research activities
- Address any questions researchers may have regarding the review process
- Address any areas of the research protocol that require clarification prior to the IBC meeting
- Assess the knowledge of research personnel who are involved in the IBC related work with regard to protocol specifics and procedures and practices associated with the biosafety level required
- Inform the IBC members of any facility issues that need to be addressed prior to approval being granted

2. BSL-2 approval:

All BSL-2 facilities must be approved by OEHS prior to initiation of work. BSL-2 approval may be done in conjunction with the IBC Biovisit.

The BSL-2 visit document is derived from the CDC/NIH booklet *Biosafety in Microbiological and Biomedical Laboratories (5th edition)* and the MiOSHA *Bloodborne Infectious Disease Standard*. This document is available for review through the OEHS Biosafety Website.

Note: For shared labs - even if the lab is “BSL-2 approved” a PI who was not part of the original BSL-2 approval process must be scheduled for a visit. This is to confirm they understand the practices, procedures and equipment needed for laboratory biosafety conditions.

D. Maintenance of IBC Approval

As specified above, it is the PI’s responsibility to maintain the IBC protocol and ensure that it accurately reflects work that is being performed. If an amendment is required to an approved protocol within the 3-year approval window, the PI must complete the following actions prior to initiating the changes:

a) e-Protocol applications: Complete the Protocol Amendment section in the e-Protocol application. Revise the protocol to include new information and details. Submit the amendment for review via e-Protocol. Amendments will initially be reviewed by the IBC Chair and Biosafety Officer.

Non-e-Protocol applications: Complete the [Protocol Amendment](#) form and submit the completed form to the Biosafety Officer. Amendments will initially be reviewed by the IBC Chair and Biosafety Officer.

b) Protocol Amendments are required for any of the following examples:

1. Change in personnel
 - Biosafety training is required.
 - New personnel should read and sign the IBC approved SOPs related to the protocol.
2. Change in research location
3. Change in agent or recombinant DNA or synthetic nucleic acids being utilized

4. Change in procedures

Note: Administrative approval by the IBC Chair and/or Biosafety Officer may be granted if response indicates no major change to the biosafety risk associated with the project. More substantial changes will require full committee review and approval.

- c) Protocols found to differ significantly from the previously approved work may require a new protocol submission.

2. Protocol expiration

If work is planned past the expiration date of the approved IBC protocol, the PI must submit a new IBC protocol for review by the full committee; no work can be performed in the absence of a current and approved protocol.

V: Unexpected Problems Reporting

A. Background

The Wayne State Biosafety Officer is required to promptly report unexpected problems to the IBC and appropriate institutional officials.

In their role as Institutional Official, the AVPR is responsible for reporting these situations to supporting agencies and appropriate regulatory authorities.

When the research is regulated by the *NIH Guidelines* the report will be sent to the NIH OSP.

Examples of Unexpected Problems:

- Failure to obtain IBC approval prior to initiating work
- Spills or accidents in BSL-2 laboratories resulting in overt exposure
- Breach of containment associated with recombinant or synthetic nucleic acid molecules, risk group 2 organisms, select agents, or toxins (e.g., a spill of BSL-2 material outside of primary containment)
- Personal injury involving recombinant or synthetic nucleic acid molecules, risk group 2 organisms, select agents, or toxins
- Illness potentially associated with recombinant or synthetic nucleic acids research, risk group 2 organisms, select agents, or toxins



- Improperly discarded recombinant or synthetic nucleic acids, risk group 2 organisms, select agents, or toxins

A frequently asked questions document on [incident reporting](#) is available through the NIH OSP.

B. Procedure

1. The WSU Biosafety Officer will notify PIs, and their Departmental Chair, when problems are identified that need to be reported to the WSU IBC for further review.
2. The PI is required to complete the “*Unexpected Problems Report*” form within 3 business days of receipt and return it to the Biosafety Officer.
3. The information in the report will be provided to the Chair of the IBC for review.
4. The IBC Chair's review will determine if the problem requires full IBC review. This will be based primarily on the nature of the incident and if notification to any supporting agencies and appropriate regulatory authorities is required.
5. If full review is required, IBC members will be asked to determine if they agree with the Chair's recommendations. In addition, IBC members will identify if the corrective actions proposed by the PI are sufficient and determine if WSU needs to implement any corrective actions at the institutional level.
6. Due to the time sensitive nature of the IBC reporting responsibilities, full IBC review of these reports does not need to be conducted during the regularly scheduled meetings.
7. Information provided in the form completed by the PI, supported by information provided by the Biosafety Officer and IBC, will be utilized to complete any official reports that need to be submitted by the Institutional Official.
8. PI and their Department Chair will be informed on the outcome of the review, provided with a copy of the official report, and if any supporting agencies and appropriate regulatory authorities are being notified.
9. Official reports will be presented to the IBC at the next convened meeting, along with any information received from supporting agencies and regulatory authorities.

VI: References

1. [NIH Guidelines](#) for research involving recombinant or synthetic nucleic acid molecules, April 2016
2. [Biosafety in Microbiology and Biomedical Laboratories, 5th edition](#)



3. MiOSHA [Bloodborne Infectious Diseases Standard](#)