

WRIGHT STATE UNIVERSITY

INSTITUTIONAL BIOSAFETY COMMITTEE GUIDELINES/POLICIES

The following policies and procedures have been adopted by the Wright State University Institutional Biosafety Committee.

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I. Mission Statement

Wright State University is committed to the safe and ethical use of biologically-derived hazardous materials.

The Institutional Biosafety Committee, as an agent for the University in such matters, shall:

- A. Assure that activities involving recombinant DNA, infectious biologicals and biological toxins meet the ethical and legal requirements for the responsible use of these agents.
- B. Establish policies and make recommendations to the University regarding such activities.
- C. Maintain and promote an open and cooperative relationship with investigators and the greater University community.
- D. Educate the Wright State University community concerning the regulatory requirements for the use of these agents.

II. IBC Charge

- A. The Committee has the general charge of supporting a healthy and safe work environment and related ethical considerations as it relates to biologically-derived hazards.
- B. The IBC is charged with:
 - 1). reviewing activities involving recombinant DNA, infectious biologicals and biological toxins,
 - 2). reviewing facilities that require oversight, and
 - 3). being aware of what agents are in which labs.
- C. The Committee also has the charge of monitoring federal, state, and local regulations and assuring WSU's compliance with these regulations.

III. Responsibilities

Wright State University is responsible for providing a safe working environment for all University activities and for compliance with all applicable federal, state, and local regulations concerning the use of biological agents, biological toxins, and recombinant DNA. Institutional responsibilities include the establishment and support of an Institutional Biosafety Committee, the appointment of an Institutional Biosafety Officer, and the establishment and support of a Department of Environmental Health and Safety.

A. Chairperson, Institutional Biosafety Committee

- 1) Ensure that the Institutional Biosafety Committee is properly constituted and fulfills its requirements under the appropriate regulations, rules, etc.
- 2) Ensure that all members of the Institutional Biosafety Committee are adequately trained in appropriate containment practices, secondary containment procedures, and accidental spill containment procedures to fulfill their responsibilities as members of the Institutional Biosafety Committee.

B. Institutional Biosafety Committee (IBC)

- 1) Advise the President, Provost, Associate Provosts, Deans, and Department Chairs on matters related to biohazards and biosafety within their respective areas of responsibility.
- 2) Develop, recommend, and implement policies and procedures for biological risk assessment and biological risk reduction throughout the University.
- 3) Develop emergency plans for the containment and resolution of accidental spills and other related emergencies with an emphasis on risk reduction, personnel protection, and environmental protection.
- 4) Oversee all research and teaching activities involving biohazardous agents including review and approval prior to initiation, annual reviews and updates, reviews of laboratory safety equipment and procedures, and certifications of compliance with all applicable rules and regulations governing the use of biohazardous materials.
- 5) As an agent of the Institution, ensure that all principal investigators are sufficiently trained in appropriate containment practices, secondary containment procedures, accidental spill containment, and their responsibilities as principal investigators.
- 6) Advise and provide technical expertise, whenever possible, to the Institutional Biosafety Officer on matters regarding biosafety.

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- 7) Conduct investigations of serious violations or problems and to make recommendations to the Associate Provost for Research for the resolution of continued non-compliance or serious infractions.

C. Institutional Biological Safety Officer (IBSO)

- 1) Conduct periodic inspections of laboratories to ensure compliance with established containment procedures.
- 2) Investigate laboratory accidents and report problems, violations, injuries, and illnesses associated with biohazardous research activities to the Institutional Biosafety Committee.
- 3) Develop and implement emergency plans for handling accidental spills and personnel contamination.
- 4) Provide advice and assistance to the Institutional Biosafety Committee and Principal Investigators concerning containment procedures and practices, laboratory security, recommended laboratory containment equipment, rules, regulations, and other matters as may be necessary.
- 5) Provide oversight and assurance that laboratory safety containment equipment is functioning properly including field testing and certification, where appropriate, of all biosafety cabinets.
- 6) Serve as a member of the Institutional Biosafety Committee.

D. Environmental Health and Safety (EHS)

- 1) Provide industrial hygiene and safety support for all laboratory operations.
- 2) Transport and dispose of all infectious wastes in compliance with all applicable federal, state, and local ordinances.
- 3) Assist, as necessary, in the emergency response, cleanup, and decontamination of biological spills and accidents.
- 4) Administer the University Occupational Health Program.

E. Research and Sponsored Programs (RSP)

- 1) Provide the necessary liaison between Principal Investigators, the Institutional Biosafety Committee, granting agencies, and regulatory agencies.

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- 2) Serve as the Office of Record for documentation involving the Institutional Biosafety Committee.
- 3) Provide all necessary documentation, forms, regulatory guidelines and regulations, etc., for Principal Investigators.

F. Laboratory Animal Resources (LAR)

- 1) Provide appropriate animal husbandry and care that meets or exceeds federal, state, and local requirements and specifications.
- 2) Ensure that animal housing systems are designed and utilized in a manner that will minimize the potential exposure of other animals or personnel to potentially biohazardous agents.
- 3) In cooperation with the investigator, the Institutional Biosafety Officer, and the Institutional Biosafety Committee, develop and implement specific standard operating procedures, in adherence to the Animal Biological Safety Level (ABSL) classification of the agent being used, addressing animal care, research procedures, and procedures in case of accident or equipment failure.
- 4) Ensure that all animal care personnel are adequately trained and aware of the potential risk associated with each agent.
- 5) Develop, in cooperation with the Institutional Biosafety Officer, emergency plans for handling accidental spills, personnel exposures, unintentional animal exposure, equipment failure, etc.

G. Principal Investigator (PI)

- 1) Ensure compliance with National Institutes of Health guidelines and all conditions stated in the protocol approved by the Institutional Biosafety Committee.
- 2) Submit protocol applications for all activities or modifications of activities involving biohazardous materials and obtain approval by the Institutional Biosafety Committee prior to initiation of the activities or modifications.
- 3) Ensure that all laboratory staff, including students, are trained in the accepted procedures in; laboratory practices, containment methods, disinfectant and disposal practices, utilization of all laboratory protective equipment (see Item H-3), and required actions in the event of accidental spill.
- 4) Develop a Laboratory Safety Plan, including an emergency action plan for accidents and spills, as an addendum to this manual, when required.

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- 5) Ensure compliance with all shipping requirements for biological agents and toxins.
- 6) Ensure proper handling and disposal of all infectious wastes as outlined in the WSU Infectious Waste Management Guide. (See Appendix D, Institutional Biosafety Manual.)
- 7) Request immunizations for all personnel when working with biological agents for which there is an effective vaccine available.
- 8) Maintain all biosafety equipment in appropriate operating condition. Decontaminate laboratory equipment prior to maintenance or disposal.
- 9) Maintain records of microorganisms and toxins used in the laboratory and biosafety cabinets.

H. Laboratory Staff (Including Students)

- 1) Conduct no activities under the research protocol until the protocol is approved by the Institutional Biosafety Committee and appropriate training is completed.
- 2) Follow all procedures and containment methods established for activities conducted.
- 3) Properly utilize all laboratory protective equipment including proper clothing, personal protective equipment, and containment devices.
- 4) Report all accidents and spills to the Principal Investigator or the Institutional Biosafety Officer as soon as possible.
- 5) Report unsafe conditions to the Principal Investigator, the Institutional Biosafety Officer, or the Institutional Biosafety Committee.

IV. Committee Composition & Structure

The following guidelines will apply to the IBC composition and structure:

- A. The chair shall be someone who has served at least one year as a member of the IBC and shall serve as chair for a term of three years. Service as chair will be renewable for additional terms if agreeable.
- B. The IBC shall have a vice-chair who will execute the responsibilities of the chair in the chair's absence.
- C. The vice chair shall be someone who has served at least one year as a member of the IBC and shall serve as vice-chair for a term of two years. Service as vice chair will be renewable for additional terms if agreeable.
- D. Committee members shall serve for a term of two years. Service will be renewable for additional terms if agreeable.
- E. Committee members who have served a term of two years and choose to discontinue service shall suggest potential replacements.
- F. The IBC shall endeavor to have a non-faculty member of the technical (e.g., Unclassified) staff represented on the IBC.

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V. Conducting Committee Business

- A. A quorum consisting of fifty percent-plus-one committee members is required to conduct business.
- B. Meetings will be held bi-monthly at a standing time and date. Additional meetings may be called as described in section II.D.
- C. Any member of the Committee may call for a role call vote on any issue(s) being reviewed, discussed, or decided by the IBC.
- D. Any member of the Committee may call for a special meeting of the IBC to deal with a topic as specified by that member. This request for a special meeting shall be made in writing to the Chair and shall include the reason(s) for the request and the topic(s) to be discussed. Such a special meeting shall be called within 14 days of the written request for such meeting.
- E. Any Committee member, acting on their behalf or on the behalf of a non-member, may call for an investigation by the IBC of laboratories or actions not in compliance with appropriate safety guidelines, for a potential protocol violation, or for work not being done on an approved protocol.

This investigation shall be conducted as described in the "Procedures for Dealing with Allegations of Noncompliance" section of this document.

- F. Management of protocols containing proprietary information.
 - 1) When the IBC reviews protocols containing proprietary information, a conflict exists between this proprietary information and the Ohio Open Records Act. The conflict is:
 - a. OSHA and NIH require records (protocol and committee notes) of who is working with what and a concise description of that work and its goals, including proprietary information, while
 - b. The State of Ohio Open Records Act requires University records be open to the public.
 - 2) To resolve the conflict, protocol applications will be accompanied by a letter which will specify whether proprietary information is included in the application.

Types of information which may be considered proprietary:

- a. New and/or novel ideas.
- b. If so specified in a written contract or agreement.

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- c. New commercial uses of a process, device or chemical.
 - d. Potentially patentable items.
- 3) This list is not inclusive. When questions arise relating to specific guidelines or matters which may be unclear, investigators should contact the Office of General Counsel.
- 4) The protocol will be discussed in executive session. The following pertain to the conduct of executive sessions.
- a. Executive session must be called for by a role-call vote.
 - b. Although records are not normally kept of executive sessions, any records that were generated during these sessions are not necessarily privileged.
 - c. Records may be confidential pursuant to Federal and/or State law (investigators provide supply written documentation/justification in support of any such confidentiality request or claim).
 - d. Only those portions of the protocol that are proprietary can be considered as such and kept confidential.
 - e. “Public meetings” and “open records” are broad terms and not yet well defined legally.
- 5) Following the executive session, the IBC will reconvene in open meeting for the purpose of a formal vote on any actions conducted during the executive session.

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VI. General IBC Approval Procedures

A. Review Procedures Information:

- 1) Anyone intending to perform any activities involving rDNA, infectious biologicals, or biological toxins must submit a protocol to the IBC for consideration, including those activities which the investigator may feel are exempt from the "guidelines".
- 2) All protocols will be reviewed via a Triage System:
 - a. The PI estimates biohazard level of their research protocol
 - b. The Institutional Biosafety Officer reviews the protocol and either agrees with the PI, reclassifies protocol or refers protocol to full Committee for reclassification
 - c. Protocols will be reviewed according to their highest Biosafety Level estimation
- 3) Following review, one (1) of three (3) determinations will be made:
 - a. Approved - Protocol was approved without restrictions.
 - b. Approved subject to restrictions - Protocol was approved with some restrictions. These restrictions will be attached and signed by the Chair. The project shall not be initiated until the restrictions have been removed or satisfied.
 - c. Disapproved - Protocol was disapproved. The reasons for disapproval are to be attached and signed by the chair.
- 4) At any meeting, action on a protocol also may be deferred (i.e., the protocol tabled) pending receipt of additional information and/or clarifications. Any such tabled protocol shall be reconsidered at the next convened meeting after receipt of requested information.

During an Administrative Review (see Item III. B., below), the Institutional Biosafety Officer may also defer action on a protocol pending additional information and/or clarification.
- 5) Multiple DNA segments can be incorporated into the same petition if they share a similar source and/or host.
- 6) IBC numbers will be assigned to all petitions regardless of review status (e.g., exempt).
- 7) P.I.'s may be invited to present their protocols to the committee and to be available to answer committee questions. In such cases, the P.I. will be excused prior to discussion and voting.

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- B. General IBC Approval Procedures for BSL-1 and BSL-2
- 1) New and renewal protocol applications for agents requiring containment conditions of BSL-1 or BSL-2 may be administratively approved by the Institutional Biosafety Officer acting on behalf of the IBC. The full Committee will require only outcome notification and consultants may be called in as necessary.
 - 2) Annual Review of BSL-1 and BSL-2 protocols are conducted administratively by the Biosafety Officer with notification of the IBC unless full Committee review is either requested by the administrative review or is mandated by other such policy.
 - 3) Investigators may appeal usage decisions by the Institutional Biosafety Officer through petitioning of the IBC followed by a full Committee hearing. The IBC may call a special meeting to expedite the appeal process if necessary
 - 4) Written descriptions of protocols that involve the use of biohazards shall be made available to all IBC members, and any member of the IBC may obtain, upon request, full committee review of those protocols.
- C. General IBC Approval Procedures for BSL-3.
- 1) New and renewal protocol applications for BSL-3 agents are approved by the IBC, using a primary reviewer designated by the Chair, and then subject to other review as may be mandated by federal, state, and local regulations.
 - 2) Protocols that have been approved pending receipt of clarifications not involving major changes may be approved by the Chair plus one other IBC member with notification of the IBC.
 - 3) Clarifications involving major changes are returned to the full committee. The IBC determines whether a clarification should come back to the committee at the time it grants approval pending clarification to the protocol.
 - 4) Annual Reviews of BSL-3 protocols are conducted by the full IBC Committee.
- D. Closures of protocols are carried out by Research and Sponsored Programs (RSP) with notification of IBC.
- E. Certifications of Current Protocol Approval are carried out by Research and Sponsored Programs (RSP) with notification of IBC.
- F. The five (5) year review of a protocol will be conducted following the “Five (5) Year Review Policy”.

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- G. Protocols involving the use of Class 4 Biohazards are not permitted.
- H. Where required, the need for multiple-committee review (e.g., IBC and LACUC) will not be waived.

VII. Procedures For Conducting a Continuing (Annual) Review of Protocols

A. Information for Continuing Review:

- 1) Two months before the anniversary of a protocol, a continuing review questionnaire will be sent to the PI. The PI will be asked for a timely response.
- 2) If a response is not obtained, the protocol will be inactivated after an appropriate warning.

B. Screening

- 1) Screening procedures for BSL-1 and BSL-2
 - a. Once continuing review information is received for BSL-1 and BSL-2 protocols, it will be reviewed by the Biosafety Officer specifically for:
 - i. Changes in the protocol.
 - ii. Changes in regulations that require modification of the protocol.
 - b. If there are no changes, or minor changes, then continuing protocol approval will be handled as a minor amendment.
 - c. If the Biosafety Officer believes the committee should review the continuing review information, the protocol will be handled as an amendment.
- 2) Screening procedures for BSL-3
 - a. Once continuing review information is received for BSL-3 protocols, it will be reviewed by the full IBC Committee specifically for:
 - i. Changes in the protocol.
 - ii. Changes in regulations that require modification of the protocol.
 - b. Any changes in protocol/procedures will be handled as an amendment.

- VIII. Procedures for Dealing with Allegations of Noncompliance (e.g., Laboratories or Actions Not in Compliance with the Appropriate Safety Guidelines, for Potential Protocol Violations, or for Work Being Done Without an Approved Protocol).
- A. Allegations, preferably in writing, shall be made to the IBC Chair, to any member of the IBC, or to the Institutional Official. In all instances, these allegations shall be immediately forwarded to the Chair. The IBC Chair is responsible for the receipt and disposition of all complaints. All allegations will remain confidential to the extent possible. When the complainant wishes to be openly identified, the IBC Chair will acknowledge receipt of the allegations to the complainant in writing.
 - B. The IBC Chair will appoint a subcommittee to determine if the complaint has sufficient substance to warrant a full investigation. All persons involved in the investigation will be informed of the purpose of the investigation and the manner in which it will be conducted. In its investigation, the subcommittee will examine all pertinent documents and procedures, will interview involved personnel and will report its findings to the Chair. If there is an indication of noncompliance, the Chair will call for an investigation by the full IBC. **If there is indication of serious noncompliance, the IBC may recommend that the Institutional Official suspend impacted activities pending the outcome of the full investigation.** The full committee investigation will be held during an executive session and all persons against whom the complaint is made will be given the opportunity to appear. Following the executive session and in an open meeting, any recommendations from the investigation will be voted upon and Committee members will be given the opportunity to present minority views. The IBC will inform all parties involved, including the complainant, of the committee's findings.
 - C. Following the investigation, the committee will recommend to the Institutional Official any appropriate remedial action warranted and an appropriate specified time period for compliance.

IX. Five (5) Year Review Policy

Each protocol shall be unique and shall be active for a maximum period of five (5) years. At the end of this five year period, it shall be automatically inactivated and all activities covered under it shall be considered complete.

Ongoing or additional activities as may be required by the specific protocol must be submitted and reviewed as a new protocol which will be assigned a new IBC number.

IBC Numbers shall be unique and not reused.

X. Facilities and Program Review

As part of its ongoing duties, the IBC needs to assure itself that its facilities oversight is adequate and that its policies and procedures, petitions, and method for conduction reviews are up to date.

To that end, the following procedures have been adapted.

A. Facilities Oversight:

Environmental Health and Safety (EHS) currently conducts audits (inspections) of those laboratories in which health and safety concerns are at issue. These inspections are conducted at least annually and involve a full spectrum of safety issues including, but not limited to, housekeeping, electrical safety, fire safety, chemical safety, biological safety, radioisotope compliance, and bloodborne pathogen compliance.

The IBC can best fulfill its mission to provide a safe working environment by providing support services to EHS, not by attempting to duplicate their efforts and possibly competing adversely with them. This support will involve:

- 1) Providing support to EHS in resolving issues of non-compliance of biological safety issues resulting from the laboratory inspections.
- 2) Acting as support/liaison between EHS and the administration in issues concerning biological safety.
- 3) Continuation of the monthly EHS report to the IBC.

B. Program Evaluation:

The IBC should conduct a periodic self-evaluation of its overall program. This review will be an agenda item at least annually. This evaluation should include a review of all aspects of the IBC program, including, but not limited to, review of its Policies and Procedures document, its petition for requesting review of activities, its administrative procedures, previous year activities, and its protocol review procedures.

XI. Principal Investigator's Training Requirements

- A. Investigators must demonstrate that they are appropriately trained to safely use biohazards.
- B. This training may be demonstrated by either completing the Wright State University biosafety training course or, if they have previous training, by completing a questionnaire in which such prior training is documented.
- C. Any such documentation of previous training will be evaluated by a standing subcommittee of the IBC.
- D. Prior to biohazard use, all training documentation must be on file with the Institutional Biosafety Officer.
- E. Principal Investigators are responsible for insuring that their staff will be trained regarding the appropriate Biosafety Level policies and procedures to employ with each agent and that this training is documented.

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XII. Miscellaneous

- A. Biosafety cabinets will receive field certification by an evaluator accredited by the National Sanitation Foundation (NSF)
 - 1) Before being put into service
 - 2) After major repairs and changes of the filter
 - 3) When relocated
 - 4) No less frequently than annually

- B. The Committee strongly encourages that all new BL-2 cabinets purchased by WSU have National Sanitation Foundation (NSF) certification.