

Wright State University

Institutional Biosafety Committee Guidelines and Policies

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

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I. Mission Statement

Wright State University (WSU) is committed to the safe and ethical use of recombinant DNA and biohazardous agents, including the use of toxins of biological origin. A biohazardous agent is an infectious agent or other substance produced by a living organism that causes disease in another living organism.

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

- A. Assure that activities involving recombinant DNA and biohazardous agents 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 WSU community.
- D. Educate the WSU 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 recombinant DNA and biohazardous materials.
- B. The IBC is charged with reviewing activities involving recombinant DNA and biohazardous agents.
- C. The Committee also has the charge of monitoring federal, state, and local regulations and assuring WSU's compliance with these regulations.

III. Responsibilities

WSU is responsible for supporting a safe working environment for all University activities and for compliance with all applicable federal, state, and local regulations concerning the use of recombinant DNA and biohazardous materials. Institutional responsibilities include the establishment and support of an IBC and Department of Environmental Health and Safety (EHS) and the appointment of an Institutional Official (IO) and Institutional Biosafety Officer (IBSO). The IO responsible for biosafety-related matters is the Vice President for Research and Graduate Studies or its institutional equivalent, hereafter referred to as IO.

- A. Chairperson, Institutional Biosafety Committee
 - 1) Ensure that the IBC is properly constituted as described in Section IV of this document and fulfills its requirements under the appropriate regulations, rules, etc.
 - 2) Ensure that all members of the IBC are appropriately trained with regard to laboratory safety and implementation of the *NIH Guidelines* and *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) recommendations.
 - 3) Conduct meetings and serve as the signatory for correspondence generated by the IBC.

- B. Institutional Biosafety Committee
 - 1) Review and approve containment levels for all research and teaching activities, or modifications of activities, conducted at or sponsored by the Institution involving recombinant DNA and biohazardous agents for compliance with the *NIH Guidelines*, BMBL, and federal, state, and local regulations.
 - 2) Periodically review recombinant DNA and biohazardous materials research for approved protocols conducted at or sponsored by the Institution to ensure compliance with the *NIH Guidelines*, BMBL, and federal, state, and local requirements.
 - 3) Ensure that all Principal Investigators (PIs) are appropriately trained for the proposed work and are aware of their responsibilities as PIs.
 - 4) Notify PIs of the results of IBC reviews and approvals.
 - 5) Report any significant problems, violations of the *NIH Guidelines*, research-related accidents, injuries, or illnesses of which the IBC becomes aware to the appropriate Institutional Official (IO) and together notify the National Institutes of Health/Office of Biotechnology Activities (NIH/OBA) within 30 days.
 - 6) Conduct investigations of serious violations or problems and to make recommendations to the IO for the resolution of continued non-compliance or serious infractions.
 - 7) Advise and provide technical expertise to WSU's Administration, IBSO, and PIs on matters related to recombinant DNA, biohazardous agents, and biosafety within their respective areas of responsibility.

- 8) Adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA and biohazardous agents research.
- 9) Develop and recommend policies and procedures for biological risk assessment and biological risk reduction throughout the University.

C. Institutional Biological Safety Officer

- 1) Conduct periodic inspections to ensure that laboratory biosafety standards are rigorously followed at Wright State University or affiliated institutions.
- 2) Provide oversight and assurance that laboratory biosafety containment equipment is functioning properly, including assurance that field testing and certification of biological safety cabinets is completed, when appropriate, at Wright State University or affiliated institutions.
- 3) Identify biological safety problems and immediately stop unsafe operations. Initiate, recommend, or provide corrective actions, verify the implementation of corrective actions, and notify the IBC.
- 4) Provide advice on laboratory security.
- 5) Provide technical advice to PIs and the IBC on research biosafety procedures.
- 6) Develop emergency plans for handling accidental spills and personnel contamination of recombinant DNA and biohazardous agents.
- 7) Investigate laboratory accidents involving recombinant DNA and biohazardous agents research and report to the IBC and the Institution any significant problems, violations of the *NIH Guidelines*, BMBL, research-related accidents, injuries, or illnesses of which the IBSO becomes aware.
- 8) Be knowledgeable about what recombinant DNA and biohazardous agents are at the Institution and where they are located.
- 9) Develop and provide biosafety training.
- 10) Serve as a member of the IBC.
- 11) Monitor federal, state, and local regulations and assure WSU's compliance with these regulations.

- D. Environmental Health and Safety
- 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 regulations.
 - 3) Assist, as necessary, in the emergency response, cleanup, and decontamination of biological spills and accidents.
 - 4) Administer the University Occupational Health Program.
 - 5) Provide to laboratory personnel mandated training as required by the Department of Transportation/International Air Transport Association prior to the shipment of recombinant DNA and biohazardous materials.
 - 6) Conduct periodic inspections to ensure that laboratory biosafety standards are rigorously followed at Wright State University or affiliated institutions.
- E. Research and Sponsored Programs (RSP)
- 1) Provide the necessary liaison among PIs, IBC, granting agencies, and regulatory agencies.
 - 2) Serve as the Office of Record for documentation involving the IBC.
 - 3) Provide all necessary documentation, forms, regulatory guidelines and regulations, etc., for PIs.
- 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 investigators, IBSO, and IBC, 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 risks associated with each biohazardous agent.
- 5) Develop, in cooperation with the IBSO, emergency plans for handling accidental spills, personnel exposures, unintentional animal exposure, equipment failure, etc.

G. Principal Investigator

- 1) On behalf of the Institution, the PI is responsible for full compliance with the *NIH Guidelines* and BMBL in the conduct of research involving recombinant DNA and biohazardous agents and for fulfilling all conditions set forth in protocols approved by the IBC.
- 2) Submit protocol applications for all activities, or modifications of activities, involving recombinant DNA and biohazardous agents. Do not initiate or modify research which requires IBC approval prior to receiving such approval, and meeting all requirements of the *NIH Guidelines*, BMBL, and other regulatory agencies as appropriate.
- 3) Report any significant problems, violations of the *NIH Guidelines*, BMBL, research-related accidents, injuries, or illnesses of which the PI becomes aware to the IBSO, LAR Director, IBC, NIH/OBA, and other appropriate authorities (as applicable) within 30 days.
- 4) Report any new information bearing on the *NIH Guidelines* to the IBC and to NIH/OBA.
- 5) Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.
- 6) Comply with NIH, federal, state, and local shipping requirements for recombinant DNA molecules and biohazardous agents and be aware that formal training and documentation may be required for certain shipments and that help is available from EHS as per Section III.D.5 of this document.
- 7) Ensure that all laboratory personnel are trained in the accepted procedures, including laboratory practices, containment methods, disinfection, waste disposal practices, personal protective equipment usage, and emergency plan implementation.
- 8) Ensure proper handling and disposal of all infectious wastes as outlined in the WSU Infectious Waste Management Guide.

- 9) Ensure that immunizations are offered for all personnel working with biohazardous agents for which an effective vaccine is available and be aware that certain vaccinations may be required to work with nonhuman primates.
- 10) Maintain all biosafety equipment in appropriate operating condition and decontaminate laboratory equipment prior to maintenance or disposal. Biosafety cabinets will receive field certification by an accredited evaluator in accordance with National Sanitation Foundation/American National Standards Institute Standard 49.
- 11) Maintain records of recombinant DNA and biohazardous agents used in the laboratory and biological safety cabinets.

H. Laboratory Personnel

- 1) Do not conduct activities with biohazardous agents until the protocol is approved by the IBC and all training is complete, as required.
- 2) Follow all established procedures, containment methods, and emergency plans for the activities conducted.
- 3) Properly utilize all personal protective equipment and containment devices.
- 4) Report all accidents and spills to the PI or PI designee as soon as possible.
- 5) Report unsafe conditions to the PI, IBSO, or IBC.

IV. Committee Composition & Structure

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

- A. The Chair is appointed by the IO. The Chair shall have 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 Vice-Chair is appointed by the IO. The Vice-Chair executes the responsibilities of the Chair in the Chair's absence. The Vice-Chair shall have 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.
- C. The IBC must be comprised of no fewer than five members selected to have the collective experience necessary to assess the safety of the proposed research.

- D. Committee members are appointed by the IO with consideration of IBC and Departmental Chair recommendations. Committee members shall serve for a term of two years. Service will be renewable for additional terms, if agreeable. Committee members who have served a term of two years and choose to discontinue service shall suggest potential replacements. Members may resign by notification to the Chair.
 - E. At least two members shall not be affiliated with the institution, apart from their membership on the IBC.
 - F. The IBC shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments involving recombinant DNA-containing plants, plant-associated biohazardous agents, and plant-associated small animals are being conducted.
 - G. The IBC shall include at least one individual with expertise in animal containment principles when experiments involving recombinant DNA-containing animals, or DNA derived therefrom, or animal-associated biohazardous agents are being conducted.
 - H. The IBC shall include at least one individual from the Dayton VA Medical Center when protocols from this center are under review.
 - I. The IBC shall endeavor to have a non-faculty member of the technical (e.g., Unclassified) staff represented on the IBC.
 - J. Alternate members are designated to represent specific member types (e.g., scientist, non-scientist, nonaffiliated representative) when any member of that type is absent from a meeting. Alternates are encouraged to attend all meetings but may only count toward a quorum and vote in the absence of that type of member. Alternate members are appointed in the same manner as regular members.
 - K. The IBC may use *ad hoc* consultants to ensure that the committee has adequate expertise and training.
- V. Conducting Committee Business
- A. A quorum consisting of a simple majority of the committee members is required to conduct business.
 - B. Meetings will be held monthly at a standing time and date. Additional meetings may be called as needed.
 - C. Any member of the Committee may call for a roll call vote on any issue(s) being reviewed, discussed, or decided by the IBC.

- D. Conflict of interest.
- 1) No member of the IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.
 - 2) If for any reason an IBC member believes they have a conflict of interest in the review or approval of a project, they may recuse themselves at any time. The IBC member will not be required to give a reason for the recusal unless they so desire. Common examples of conflicts of interest include but are not limited to mentoring, supervisory, or recent collaborative relationships between the IBC member and the project investigators.
- E. 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.
- F. 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 being conducted without an approved protocol. This investigation shall be conducted as described in the Section VIII of this document.
- G. Management of protocols containing proprietary information.
- 1) When the IBC reviews protocols containing proprietary information a conflict may exist between this proprietary information and the Ohio Open Records Act as follows:
 - a. The Occupational Safety and Health Administration (OSHA) and NIH require a written record about who is working with what biohazardous agents and a concise description regarding the nature of the work and its goals. This information may be proprietary, while;
 - b. The State of Ohio Open Records Act requires University records be open to the public.
 - 2) To resolve the conflict, the applicant will submit a letter along with the protocol application specifying that proprietary information is contained 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.
 - c. New commercial uses of a process, device, or chemical.
 - d. Potentially patentable items.
- 3) The above list is not inclusive. When questions arise relating to specific guidelines or matters which may be unclear, investigators should contact the Director of Technology Transfer and Development.
 - 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. In this case, investigators shall provide written documentation to justify any such confidentiality request or claim.
 - d. Only those portions of the protocol that are proprietary can be considered as such and kept confidential.
 - 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.

VI. General IBC Approval Procedures

A. Review Procedures Information:

- 1) Anyone intending to perform activities involving recombinant DNA or biohazardous agents must submit a protocol to the IBC for consideration, including those activities which are exempt from the *NIH Guidelines*.
- 2) IBC numbers will be assigned to all petitions upon submission.
- 3) All new protocols will be pre-reviewed by the IBSO.
 - a. PIs will submit protocols to the IBSO by the established deadline.

- b. The IBSO will provide feedback on the completeness and clarity of the application to the PI who will then make any necessary changes to make it suitable for IBC review by the established deadline. The IBSO's signature must be obtained on the biosafety application.
 - c. Protocols will be reviewed according to their highest biosafety level estimation.
- 4) For protocol applications reviewed by the IBC, the Chair will assign a primary reviewer for the application, who will present the application to the committee and provide a written synopsis of the protocol, including any concerns or questions that must be addressed.
- 5) Following review, one (1) of four (4) determinations will be made:
 - a. Approved - Protocol was approved without restrictions.
 - b. Approved pending modifications - 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.
 - d. 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.
- 6) PIs may be invited to present their protocols to the committee and to be available to answer committee questions. In such cases, the PI will be excused prior to discussion and voting.
- 7) Investigators may appeal usage decisions by petitioning the IBC. The IBC may call a special meeting to expedite the appeal process if necessary.
- 8) Clarifications involving minor changes may be approved by the IBSO and IBC Chair with notification of the IBC.
- 9) Clarifications involving major changes will be approved by the IBC. The IBC will determine whether the clarification is considered to be major at the time of the original review.

- B. Approval Procedures for BSL-1
 - 1) New protocol applications subject to Sections III-A through III-E of the *NIH Guidelines* must be reviewed by the IBC.
 - 2) New protocol applications not subject to Sections III-A through III-E of the *NIH Guidelines* may be administratively approved by both the IBSO and IBC Chair acting on behalf of the IBC. The IBC will require only outcome notification. Consultants may be called in as necessary.
- C. All new protocol applications for agents requiring containment conditions BSL-2 or higher will be reviewed by the IBC.
- D. BSL-4 activities are not permitted.
- E. Protocol changes (amendments)
 - 1) All changes must be approved by the IBC. Changes include but are not limited to changes in biohazardous agent, biosafety level, personnel, project location, and procedures. Substantial changes may require a new protocol.
 - 2) The IBC-approved amendment form must be used.
 - 3) The procedures for approving amendments are the same as those described above for new protocols, with the exception that minor personnel and project location changes may be administratively approved by both the IBSO and IBC Chair acting on behalf of the IBC.
- F. Closures of protocols are carried out by RSP with notification to the PI and IBC. PIs will be notified three months in advance of a pending protocol closure, except in cases where the PI initiated the closure.
- G. 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 closed with a three month advance notice to the PI. Ongoing and future activities 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.
- H. Where required, the need for multiple-committee review (e.g., IBC and LACUC) will not be waived.

VII. Continuing (Annual) Review of Protocols

- A. Information for Continuing Review:
 - 1) Two months before the yearly 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 closed after a 30-day grace period.
- B. Continuing review applications will be evaluated to ensure that the protocol is still active, that no changes have been made to the protocol, that no accidents or injuries have occurred over the review period, that training and safety equipment are up to date, and that changes in regulations do not require modification of the protocol.
- C. Continuing review applications for projects subject to Sections III-A through III-E of the *NIH Guidelines* must be reviewed by the IBC.
- D. Continuing review applications for projects not subject to Sections III-A through III-E of the *NIH Guidelines* may be administratively approved by both the IBSO and IBC Chair acting on behalf of the IBC. The IBC will require only outcome notification.

VIII. Procedures for Dealing with Allegations of Noncompliance (e.g., Laboratories or Actions Not in Compliance with the Appropriate Safety Guidelines, Potential Protocol Violations, or Work Being Done Without an Approved Protocol).

- A. Allegations, preferably in writing, shall be made to the IBC Chair, any IBC member, IBSO, or the IO. In all instances, these allegations shall be immediately forwarded to the Chair.
- B. 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.
- C. 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.

- D. 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 entire IBC. If there is indication of serious noncompliance, the IBC may recommend that the IO suspend impacted activities pending the outcome of the full investigation.
 - E. The IBC 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, recommendations from the investigation will be voted upon, and IBC 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.
 - F. Following the investigation, the committee will recommend to the IO any appropriate remedial action warranted and an appropriate specified time period for compliance.
- IX. Facilities and Program Review
- A. Facilities:

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 Review:

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 Guidelines and Policies document, petition for requesting review of activities, forms, administrative procedures, previous year activities, and protocol review procedures.