West Virginia School of Osteopathic Medicine

Institutional Biosafety Committee Procedures

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Abbreviations:

ABSL – Animal Biological Safety Level
AVPRSP - Assistant Vice President of Research and Sponsored Programs
BMBL – Biosafety in Microbiological and Biomedical Laboratories
BSL – Biosafety level
IACUC - Institutional Animal Care and Use Committee
IBC – Institutional Biosafety Committee
IBSO – Institutional Biosafety Officer
IRB - Institutional Review Board
LAR – Laboratory Animal Resources
LD – Lethal Dose
NIH – National Institutes of Health
NIH Guidelines - NIH Guidelines for Research Involving Recombinant DNA Molecules
OBA – Office of Biotechnology Activities
ORSP - Office of the Research and Sponsored Programs
OSP – Office of Science Policy
PI - Principal Investigator
RG - Risk group
VPAER - Vice President for Administration and External Relations
WVSOM – West Virginia School of Osteopathic Medicine

I. DEFINITIONS

A. "Biohazardous agent" means an infectious agent or biological toxin that has the potential to cause deleterious effects in living organisms.

B. "Biosafety Levels (BSL)" means graded specifications (BSL1 through BSL4) of containment facilities and practices stipulated in the 6th Edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL[1]) and the NIH Guidelines[2]. The four levels address the risk associated with biohazardous agents.

C. "Biological toxin" means any molecule produced by a biological organism that has a poisonous or injurious neurological or physiological effect on living organisms exposed to the agent.

D. "Containment" means the confinement of a biohazardous agent that is being cultured, stored, manipulated, transported, or destroyed in order to prevent or limit its contact with living organisms.

E. "Human tissues" means human cells, tissues, body fluid, and human-derived cell lines. Human tissues may harbor bloodborne pathogens. Specific information regarding bloodborne pathogens can be found in the WVSOM Bloodborne Pathogens Guidelines and Exposure Control Plan[3], OSHA Bloodborne Pathogens and Needlestick Prevention website[4], and 29 CFR 1910.1930[5].

F. "Non-Human Primate (NHP) tissues" means NHP cells, tissues, body fluid, and NHP-derived cell lines. NHP tissues may harbor bloodborne pathogens. Specific information regarding bloodborne pathogens can be found in the WVSOM Bloodborne Pathogens Guidelines and Exposure Control Plan[3] and OSHA Bloodborne Pathogens and Needlestick Prevention website[4].

G. "Infectious agent" means organisms, viruses, or prions that are capable of producing infection or infectious disease in living organisms.

H. "Protocol" means a document that includes the necessary information, as outlined in III.A. *Registration of Protocols* of this document, for the IBC to properly assess the biosafety risk and biocontainment practices of a research project.

I. "Recombinant DNA and Synthetic Nucleic Acid Molecules" means, according to the NIH Guidelines[2]:
   (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
   (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids; or
   (iii) molecules that result from the replication of those described in (i) or (ii) above.

J. "Risk Groups (RG)" means graded specifications (RG1 through RG4) of biohazards as defined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL[6]) and the NIH Guidelines[7]. The four groups address the risk associated with the biohazardous agent.

K. "Select Infectious Agent or Select Biological Toxin" means infectious agents and biological toxins that have the potential to pose a severe threat to public health and safety. Lists of agents are listed in the Federal Select Agent Program[8]. At the time of this publication, WVSOM does not permit research with select infectious agents and select biological toxins.

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[1] https://www.cdc.gov/labs/BMBL.html; Section IV
[2] https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/; Appendix G-II
[3] https://www.wvsom.edu/safety/bloodborne-pathogens-guidelines
[4] https://www.osha.gov/SLTC/bloodbornepathogens/
[5] https://www.osha.gov/laws-regs/regulations/standardnumber/1910
[6] https://www.cdc.gov/labs/BMBL.html; Section II
[7] https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/; Appendix B, Table 1
[8] https://www.cdc.gov/selectagent/index.html; 42 CFR Part 73

II. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

The Institutional Biosafety Committee (IBC) is charged by the National Institutes of Health to ensure that research conducted at WVSOM is in compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules[6]. The IBC is further charged to assess the biosafety risk of research that uses potential biohazardous materials and/or biologics (CDC/NIH Biosafety in Microbiological and Biomedical Laboratories – 6th Edition[9]), research experiments that include select agents (Federal Select Agent Regulations[10]), and research that includes the potential exposure to bloodborne pathogens[11]. The IBC ensures that research conducted at WVSOM is in compliance with applicable federal regulations and guidelines, granting agency guidelines, and WVSOM policies and procedures and will provide input on the use of biohazardous agents to safeguard the health and safety of WVSOM personnel, students, the community, and the environment.

A. Committee goals

1. Ensure that reasonable and proper precautions and procedures are used in WVSOM research activities to minimize and/or eliminate the risk of occupational exposure to biohazardous agents.
2. Assess risk and containment of biohazardous agents in an effort to mitigate potential exposures to WVSOM personnel and the Lewisburg community.
3. Assist and advise WVSOM principal investigators (PIs) and research personnel regarding appropriate international, federal, state and local biosafety regulations or guidelines associated with research.

B. Committee responsibilities

1. Adhere to the specific responsibilities set forth in the NIH Guidelines as they pertain to recombinant or synthetic nucleic acid molecules.[12]
2. Verify and/or assign containment levels of biohazardous agents in accordance with the NIH Guidelines, Biosafety in Microbiological and Biomedical Laboratories Manual– 6th Edition[13], Federal Select Agent Regulations[14] and OSHA.[15]
3. Review protocols for each project or each research laboratory using biohazardous agents as outlined in section III (IBC Procedures) of this document.
4. Assess laboratory design, physical facilities, containment levels, facility procedures and practices, and personnel training as it pertains to biosafety.
5. Oversee monitoring of biosafety and containment practices.
6. Work interactively with the PIs, research personnel, and ORSP on the following:
   a) Emergency plans related to biohazardous materials
   b) Feedback on templates, examples, and guidance on protocols.
7. Provide feedback on institutional policies regarding biohazardous agents, risk assessment, and containment.
8. Provide timely reports to VPAER regarding any Federal or State-mandated reporting requirement.[16]
9. Establish criteria and practices for IBC business as outlined in section II.C *Membership* and II.D *Quorum* of this document.

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[9] https://www.cdc.gov/labs/BMBL.html
[10] https://www.selectagents.gov/regulations.html
[11] https://www.osha.gov/SLTC/bloodbornepathogens/ and 29 CFR 1910.1030
[12] NIH Guidelines; Section I-C
[13] https://www.cdc.gov/labs/BMBL.html
[14] https://www.selectagents.gov/regulations.html
[15] https://www.osha.gov/SLTC/bloodbornepathogens/ and 29 CFR 1910.1030
[16] NIH Guidelines; Section IV-B-2-a-(3)

10. Update and review the WVSOM Biosafety Manual; an institutional handbook that outlines procedures necessary to establish safe practices for the use of biohazardous agents; the safe procurement, use, storage, and disposal of biohazardous agents; and the preparedness and response to biohazard emergencies.
11. Review this document (Institutional Biosafety Committee Procedures) at least annually and update as needed when there are changes to the NIH guidelines, BMBL, OSHA bloodborne pathogen regulations, select agent regulations, or institutional policy.
12. Collaborate with the WVSOM Safety and Security Committee, the Office of the Vice President for Administration and External Relations (VPAER), ORSP, the Institutional Animal Care and Use Committee (IACUC), the Institutional Review Board (IRB), and other institutional groups to ensure compliance with federal, state and local biosafety regulations.

C. Membership

1. The IBC membership is based on the WVSOM Faculty Handbook and includes members as outlined in the NIH Guidelines. [17,18]
    a) The IBC must be composed of at least five voting members who collectively have experience and expertise, at a minimum, in recombinant synthetic nucleic acid technology, biological pathogens and toxins, and the identification of potential risks to public health and the environment.
        i. The chair of the IBC will be a faculty member appointed by the VPAER to an unlimited term.
        ii. At least two (2) additional faculty members at large will be appointed by the VPAER, based on recommendations from the IBC Chair, AVPRSP, and other input; each serving a staggered three-year term, with re-appointment as appropriate.
        iii. At least two (2) external members, not affiliated with the institution, who represent the community with respect to health and/or protection of the environment, will be appointed annually by the VPAER, upon input from the IBC.
        iv. Ex-officio members, without vote, will include the AVPRSP, the Supervisor of Laboratory Animal Resources, and the Research Integrity and Compliance Administrator.
    b) At least one member must have expertise in plants, plant pathogens, or plant pest containment when protocols are submitted that are covered by Appendix L of the NIH Guidelines.
    c) At least one member must have expertise in animal, physical, and biological containment for recombinant or synthetic nucleic acid molecule research involving animals when protocols are submitted that are covered by Appendix M of the NIH Guidelines.
    d) A Biological Safety Officer (BSO) will become a permanent voting member if WVSOM and the IBC approve research involving recombinant/synthetic nucleic acid/select agents at BSL3/4 or involving large scale protocols (>10 L). The BSO will perform duties as described in the NIH guidelines.[19]
    e) Ad hoc consultants or external reviewers with appropriate expertise may be solicited by the IBC Chair on an as needed basis.

D. Quorum

1. For review of protocols involving non-exempt experiments covered by the NIH Guidelines[20], a quorum shall consist of no fewer than half of the voting IBC membership and must include at least one (1) of the external, non-affiliated members.

[17] https://www.wvsom.edu/policies/faculty-handbook
[18] NIH Guidelines; Section IV-B-2
[19] NIH Guidelines; Section IV-B-3
[20] NIH Guidelines; Section III

a) These full committee meetings are conducted following the procedures outlined in section III.B.3 of this document.

b) Members may attend via video or tele-conferencing.

2. For all other IBC business, including the review of protocols involving exempt experiments covered by the NIH Guidelines, the IBC shall meet according to section III.B *Review of Protocols* of this document, as determined by the IBC Chair.

3. Full IBC meetings shall generally be open to the public.[21]

   a) The IBC Chair will determine when the protection of privacy or proprietary interests are necessary prior to a meeting and inform IBC members in writing as to which material is considered confidential. Any content deemed confidential, including conflict of interest reports, fall under the purview of the WVSOM confidentiality agreement.[22]

   b) Full IBC meeting minutes shall be available to the public by request, following WVSOM Intuitional Policy GA-34: Public Record Requests[23] and the NIH Guidelines.[24]

4. IBC members will not vote upon any research protocol for which they or an immediate family member serve as a PI or co-investigator or for which they may have a direct financial or other conflict of interest.[25]

   a) Each IBC member must self-report such interests to the IBC Chair prior to review of any protocol.

   b) IBC voting members (by majority vote) will determine if involuntary recusal is necessary for members that refuse to voluntarily recuse themselves from protocols for which they have a conflict of interest. The IBC may consult with the Conflict of Interests (COI) Committee on such matters.

5. Quorum for IBC business unrelated directly to protocols is defined as a majority of the voting IBC members. Additionally, deliberation and vote can be done online or via e-mail with minutes recorded if a vote is taken. However, all members must be invited to the deliberation and be permitted to engage in the discussion and vote.

E. Records

Official records of IBC activities and deliberations will be retained by the ORSP. All records shall be accessible to IBC members.

III. IBC PROCEDURES

At the time of this publication, WVSOM does not permit the conduct of research with the following biohazardous materials:

1. RG3 or RG4 (BSL3 or BSL4) agents[26]
2. Select infectious agents or select biological toxins[27]
3. Large scale research (>10 L)[28]

[21] NIH Guidelines; Section IV-B-2-a-(6)
[22] See Human Resources for a copy of your confidentiality agreement
[23] https://www.wvsom.edu/policies/ga-34
[24] NIH Guidelines; Section IV-B-2-a-(7)
[25] NIH Guidelines; Section IV-B-2-a-(4)
[26] NIH Guidelines; Appendix B
[27] https://www.selectagents.gov/regulations.html
[28] NIH Guidelines; Section III-D-6

A. Registration of Protocols

1. All research involving the use or storage of biohazardous agents listed in a) through e) of this section must be approved by the IBC and registered with ORSP prior to their possession and use. This includes protocols that are considered exempt in the NIH guidelines.[29]
2. Note that a single protocol may include all types of materials listed in a) through e) of this section, if some or all are utilized in the experimental protocol (e.g. rDNA, use of biological toxins, use of a human cell line, and use of animals).
3. Registration is initiated by PI through the submission of an electronic biosafety protocol application.[30]
4. The PI is responsible for conducting the initial risk assessment as part of the registration process and propose the proper work practices and containment requirements to use the biohazardous materials. The risk assessment should identify features of microorganisms as well as host and environmental factors that influence the potential for workers to have a biohazard exposure and to determine the appropriate biosafety level (see appendix A: faculty resources for assistance with risk assessment and/or consult with an IBC member).
5. The following are biohazardous agents that require submission of protocols to the IBC:

a) Recombinant or Synthetic Nucleic Acids

i. Registration requires the following:
   a. Date of submission
   b. Contact information of the PI
   c. Identification of personnel involved in the project
   d. Information regarding the following:
      i. Source of nucleic acids
      ii. Nature of the inserted nucleic acid sequences (e.g. plasmid, viral vector, synthetic)
      iii. Host cells (e.g. DH5α, HeLa cells)
      iv. Name of vectors
      v. If expression of a foreign gene, the gene product (protein/nucleic acid) and function (e.g. toxin, oncogene)
   e. An overview of the research that will be conducted using recombinant or synthetic nucleic acids
   f. An assessment of the biosafety concerns and practices
   g. Submission of a laboratory-specific biosafety manual when RG2 agents are registered

b) Infectious Agents (organisms, viruses, or prions)

i. If recombinant or synthetic nucleic acids will be inserted into an infectious agent, section III.A.5.a) *Recombinant or Synthetic Nucleic Acids* must also be completed.

ii. Registration requires the following:
   a. Date of submission
   b. Contact information of the PI
   c. Identification of personnel involved in the project
   d. Identification of the infectious agent, infectious dose (if known), and common routes of transmission (Each infectious agent will be registered on a separate registration page. Mutants/recombinants can be listed on the same page)
   e. An overview of the research that will be conducted using the infectious agent

[29] NIH Guidelines; Sections III-F
[30] https://wvsom.my.irbmanager.com/

f. An assessment of the risk group associated with the infectious agent, biosafety level of the laboratory where the work will be conducted, and biosafety practices followed in the course of the experimental program
g. Submission of a laboratory-specific biosafety manual when RG2 agents are registered

c) Biological Toxins

i. If recombinant or synthetic nucleic acids encoding toxins will be cloned and expressed into any cell line, then section III.A.5.a) *Recombinant or Synthetic Nucleic Acids* must be completed.

ii. Research involving the acquisition and use (not cloning/expression) of biological toxins with an LD_{50} between 0.1µg/kg - 100µg/kg body weight are covered under this section.

iii. Research involving the acquisition and use (not cloning/expression) of biological toxins with an LD_{50} >100µg/kg body weight is exempt from IBC registration.

iv. Registration requires the following:
a. Contact information of the PI
b. Identification of personnel involved in the project
c. Identification of the biological toxin (each biological toxin will be registered on a separate registration page; mutated toxins can be listed on the same page; e.g. catalytic null)
d. An overview of the research that will be conducted using the biological toxin
e. An assessment of the biosafety level of the laboratory where the work will be conducted and biosafety practices followed in the course of the experimental program

d) Human or Non-Human Primate (NHP) Tissues and Cell Lines

i. If recombinant or synthetic nucleic acids will be inserted into a human or NHP cell/tissue, then section III.A.5.a) *Recombinant or Synthetic Nucleic Acids* must also be completed.

ii. Materials in this category are designated as potential bloodborne pathogens and are registered as RG2 agents.[31]
a. Annual bloodborne pathogen training is required by OSHA[32] and is evaluated by the WVSOM Safety Committee as outlined in the WVSOM Bloodborne Pathogens Guidelines and Exposure Control Plan.[33]

iii. Materials in this category are divided into two subcategories:
a. Clinical-based manipulations
i. The clinical manipulation of material will follow universal precautions under the procedures outlined by the non-WVSOM clinical facility (e.g. blood draw at Robert C. Byrd Clinic).
ii. Standard operating protocols from the non-WVSOM clinical facility where the material will be collected and/or manipulated shall be submitted with the protocol.
b. Laboratory-based research manipulations
i. This material shall follow procedures outlined below in this category.

iv. Registration requires the following:
a. Contact information of the PI
b. Identification of personnel involved in the project
c. Identification of the human/NHP tissue/cell line (each tissue/cell line will be registered on a separate registration page; identical cells with altered genetic material [mutations/deletions/insertions, etc.] can be listed on the same page)

[31] https://www.cdc.gov/labs/BMBL.html; Appendix H
[32] https://www.osha.gov/SLTC/bloodbornepathogens/
[33] https://www.wvsom.edu/safety/bloodborne-pathogens-guidelines

d. An overview of the research that will be conducted using the human/NHP tissue/cell line
e. An assessment of the risk group associated with the human/NHP tissue/cell line, biosafety level of the laboratory where the work will be conducted, and biosafety practices followed in the course of the experimental program
f. Submission of a laboratory-specific biosafety manual

e) Experiments in Animals

i. IBC approval is necessary for the use of biohazardous agents in animals and is required prior to review by the Institutional Animal Care and Use Committee (IACUC).[34]

ii. If recombinant or synthetic nucleic acids will be inserted into animals, then section III.A.5.a) *Recombinant or Synthetic Nucleic Acids* must also be completed.

iii. Registration requires the following:
a. Contact information of the PI
b. Identification of personnel involved in the project
c. Identification of the animals utilized in the project (include proposed genotype if transgenic experiments will be produced)
d. Animals of the same species will be registered on the same registration page
e. An overview of the research that will be conducted, to include when necessary:
i. Use of infectious agent, toxin, or cell type in the animal (also complete III.A.5.b), III.A.5.c), respectively)
ii. The development of transgene model (include proposed genotype)
f. An assessment of the risk group associated with the transgenic animal, biosafety level of the laboratory where the work will be conducted, and biosafety practices followed in the course of the experimental program
g. Submission of a laboratory-specific biosafety manual when BSL2 experiments are proposed

iv. In the case of breeding (only) of genetically modified animals as per the NIH Guidelines (Generation of BL1 Transgenic Rodents via Breeding[35]), the IACUC will inform the IBC of such IACUC protocol applications. Though such work is exempt from NIH Guidelines, the IBC may request to review the IACUC protocol for appropriate containment and biosafety considerations, as per the WVSOM IACUC SOP "Genotypic and Phenotypic Monitoring of Genetically Modified Animal".

B. Review of Protocols

Protocols submitted to the IBC are subject to administrative review, expedited review, or full IBC review. Protocols are submitted via the electronic biosafety protocol application.[36]

1. Administrative review

a) The following protocols may receive administrative review (this is not an exhaustive list; please consult the IBC Chair for clarification):

i. Recombinant DNA or synthetic nucleic acid projects that fall under the "exempt" category as defined in the NIH Guidelines[37]

ii. RG1 agents[38]

iii. Biological toxins with an LD_{50} between 0.1µg- 100µg/kg body weight

iv. Primary human and NHP tissues/cell lines that have been shown to be free of RG2 agents

[34] IACUC Document: Principles of ABSL-2 Use in Animals
[35] NIH Guidelines: Appendix C-VIII
[36] https://wvsom.my.irbmanager.com/
[37] NIH Guidelines; Section III-F
[38] NIH Guidelines; Appendix B-I

v. Standard (characterized) transformed human or NHP tissue/cell lines

b) Protocols approved by administrative review are renewed annually. (See III.B.5)

c) A PI may request, in writing to the IBC Chair, full IBC review of their protocol for any reason.

d) Procedures

i. Administrative review is performed generally within five (5) business days after submission of a protocol.

ii. A voting IBC member will be assigned to evaluate the protocol by the IBC Chair.

iii. The full IBC will be notified, via e-mail, that a protocol has been assigned administrative review and to whom.

iv. Any voting member may request a full IBC or expedited review of the protocol within three (3) business days of initial notification.

v. The selected reviewer will send a written decision (e.g. e-mail) to the IBC Chair.

e) Decisions

i. Approval of protocols
   a. Written confirmation of approval is sent to the PI.

ii. Modification of protocols
   a. Protocols that require modification prior to approval are referred back to the PI for additional information or documentation.

iii. Referral to full IBC
   a. Protocol approval may not be denied through the administrative review process.
   b. If the reviewer believes the protocol cannot either be approved directly or approved following modifications, a full IBC review is initiated.

f) For record purposes, the final results of an administrative review are reported to the IBC and ORSP through email notification. Original documents are submitted to ORSP for record keeping.

2. Expedited Review

a) Any protocol that does not fall under the purview of Section IIIA-E of the NIH Guidelines: Experiments Covered by the NIH Guidelines, may receive expedited review. (please consult the IBC Chair for clarification)

b) The PI may request, in writing to the IBC Chair, a full IBC review of their protocol.

c) The IBC Chair may determine if an initial or amended protocol will receive an expedited review, even if a PI has not requested it.

d) Protocols approved by expedited review are renewed annually. (See III.B.5)

e) Procedures

i. Expedited review is performed by a panel that includes the IBC Chair and two (2) additional voting members (selected by the chair) upon receipt of an electronic protocol submission, generally within five (5) business days.
   a. The full IBC will be notified, via e-mail, that a protocol has been assigned expedited review and to whom.
   b. Any voting member may request a full IBC review of the protocol within three (3) business days of initial notification.

ii. If necessary, the IBC Chair will seek the input of content experts from within or outside the institution. These individuals are without vote.

f) Decisions

i. Approval of protocols
   a. A protocol is approved by majority vote.
   b. Written confirmation of approval is sent to the PI.

ii. Modification of protocols
   a. Conditional Approval
      1. A protocol is conditionally approved by majority vote.
      2. Protocols that require simple modification(s) prior to approval are referred back to the PI for modification.
      3. Once the PI reports completion of the modification(s) to the IBC Chair, the IBC Chair provides written confirmation of approval to the PI, IBC, and ORSP.
   b. Major Modification/Edits Required
      1. The protocol has not been approved as submitted and requires major edits/modifications.
      2. Written suggestions/edits are sent to the PI within five (5) business days of the vote.
      3. Edits/modifications must be submitted as amendments to the protocol to the three-member expedited review panel. If the panel deems modifications acceptable by majority vote, the protocol is approved. See III.B.2.e)i.
      4. Commencement of the research project and/or ordering of materials to campus may not occur until the PI is provided an approval letter signed by the IBC Chair/designee.
      5. The PI may appeal this decision as outlined under section III.B.7.

iii. Rejection of protocols
   a. Protocol approval may not be denied through the expedited review process.
   b. If the expedited review panel believes the protocol cannot either be approved directly or approved with modifications, a full IBC review is initiated.

g) For record purposes, the final results of an expedited review are reported to the IBC and ORSP through email notification. Original documents are submitted to ORSP for record keeping.

3. Full IBC review

a) The following protocols receive full IBC review (this is not an exhaustive list; please consult the IBC Chair for clarification).

i. Non-exempt experiments (Section III A-E of NIH Guidelines) involving recombinant or synthetic nucleic acids.[39]

ii. Clinical trials involving human gene therapy.

iii. Experiments that introduce infectious agents into human subjects.

b) Protocols approved by full IBC review are renewed annually. (See III.B.5)

c) Procedures

i. A quorum (section II.D) meets as needed, scheduled by the IBC Chair, and reported to the IBC and ORSP through email notification.

ii. The full protocol is delivered (or software access given) to all members of the IBC no less than five (5) business days prior to the scheduled meeting.

iii. Notice of an IBC full meeting is displayed on a public forum (e.g. WVSOM website, campus electronic message boards) no less than five (5) business days prior to the scheduled meeting.

[39] NIH Guidelines Section III-A through III-E

d) Decisions

i. Approval of protocols
   a. Protocol is approved by majority vote.
   b. IBC approval is provided in the form of an approval letter signed by the IBC Chair/designee sent to the PI within five (5) business days of the committee vote.
   c. Upon receipt of the approval letter, commencement of the research project and ordering of materials to campus may occur.

ii. Modification of protocols
   a. Conditional Approval
      1. Approved by majority vote.
      2. Protocols that require simple modification(s) prior to approval are referred back to the PI for modification.
      3. Once the PI reports completion of the modification(s) to the IBC Chair, the IBC Chair provides written confirmation of approval to the PI, IBC, and ORSP
   b. Major Modifications/Edits Required.
      1. This protocol has not been approved by the IBC as submitted and requires major edits/modifications.
      2. Written suggestions/edits are sent to the PI within five (5) business days of the committee vote.
      3. The PI's response(s) (edits/modifications) must be submitted as amendments to the protocol for full IBC review. If the IBC deems the modifications acceptable by majority vote, the protocol is approved. See III.B.3.d).i.
      4. Commencement of the research project and/or ordering of materials to campus may not occur until the amended protocol is approved by the full IBC and the PI receives an approval letter signed by the IBC Chair/designee.
      5. The PI may appeal this decision as outlined under section III.B.7.

iii. Rejection of protocols
   a. This protocol has been rejected by majority vote and cannot be modified.
   b. The IBC Chair provides a written explanation to the PI within five (5) business days of the committee vote.
   c. Commencement of the research project and/or ordering of materials to campus may not occur.
   d. The PI may appeal this decision as outlined under section III.B.7.

4. Amendments to Protocols

a) Any significant modification (change(s) that would require administrative, expedited, or full IBC review) from an approved protocol must be reported as an amendment via the electronic biosafety protocol application[40] prior to enacting the new modifications (consult IBC Chair for clarification).

b) All amendments will be reviewed by the IBC Chair/designee upon receipt of a protocol submission, generally within five (5) business days.

c) The IBC Chair will determine whether the amendment requires administrative review, full IBC review, or expedited review.

i. The procedures outlined in III.B.1. will be followed for amendments that receive administrative review.

ii. The procedures outlined in III.B.2 will be followed for amendments that receive expedited review.

iii. The procedures outlined in III.B.3 will be followed for amendments that receive full IBC review.

[40] https://wvsom.my.irbmanager.com/

5. Renewal of Protocols (Annual Updates)

    a) An annual update/renewal shall be completed by the month and day of the original approved protocol.

    b) Approximately 45 calendar days prior to expiration, the PI will receive a reminder email to complete the electronic annual update.

    c) Renewals with no modifications are approved by the IBC Chair.

    d) Renewals with modifications are considered amended protocols and are reviewed as per III.B.4. *Amendments to Protocols.*

    e) Protocols not renewed annually will expire.

        i. For record purposes, expired protocols are reported to the PI, IBC, and ORSP through email notification within five (5) business days of expiration.

            a. In the event of the inadvertent expiration of a protocol, the PI may appeal, within 30 calendar days of expiration, in writing to the IBC Chair.

        ii. The research project and/or ordering of materials to campus may not proceed until the protocol is renewed by the IBC Chair/designee.

6. Appeals

    a) PI initiated appeals

        i. In the event a protocol has been given a conditional approval, modification required, or outright rejection, the PI has the option of submitting an appeal within 30 calendar days of protocol notification.
            a. The following should be submitted to the IBC Chair:
                i. A written explanation that addresses why the protocol does not require edits/modification or should not be rejected.
                ii. Additional pertinent materials as evidence to show why an approval should be given without modifications or should not have been rejected.
                iii. Materials as outlined in Section III.A. *Registration of Protocols* that should have been included in the initial application will not be accepted.
            b. Procedures
                i. The full IBC shall convene to review the original protocol and written appeal.
                ii. The appeal will either be approved or rejected by majority vote. This decision is final
                iii. The IBC Chair/designee shall notify the PI and ORSP of the IBC's decision within five (5) business days of the vote.

C. Reporting of spills, exposure, or accidents

Any spills, exposures, or accidents in the laboratory or serious adverse events (SAEs) in clinical studies under an IBC approved protocol must be reported to the ORSP/designee within 24 hours.

IV. ROLES and RESPONSIBILITIES

A. Principal Investigator

Each PI is ultimately responsible for the protocol, registration, training, and safe handling of all biohazardous research agents and materials used by their personnel. PI responsibilities include, but are not limited to, the following:

1. On behalf of the institution, be responsible for full compliance with the NIH Guidelines in the conduct of recombinant or synthetic nucleic acid molecule research. [41]

[41] NIH Guidelines; Section IV-B-7

2. Protocols must be approved/registered **prior** to initiation or ordering of biohazardous agents.
3. Protocols are active for one year. Protocols must be renewed annually by the date (month and day) that the original protocol was approved.
4. Changes (amendments) to approved protocols that would require IBC review must be approved prior to implementation.
5. All adverse incidents that involve biohazardous agents must be reported to ORSP, including spills, exposures, and accidents.
6. Shall not disseminate nucleic acid or biohazardous agents or materials including associated cell lines outside the institution without appropriate authorizations.
7. In the event a faculty researcher leaves the institution, ends their research project(s), or simply moves to a different location on campus, the PI is responsible for arrangements to provide for appropriate and compliant transfer, storage, and/or disposal of relevant biohazardous material.

B. IBC Chair

The IBC Chair/designee is responsible for conducting, and properly documenting, the business of the IBC. Responsibilities include, but are not limited, to those listed:

1. Provide expert advice to IBC members, faculty, staff, and administration concerning biosafety-related activity.
2. Schedule IBC meetings.
3. Determine if an initial or amended protocol will receive an administrative review, expedited review, or full IBC review.
4. Provide written decisions to IBC, PI, and ORSP as outlined in III. *IBC Procedures* of this document.
5. Determine, in consultation with the AVPRSP, HR, or other appropriate administrators, when the protection of privacy or proprietary interests are necessary prior to a full IBC meeting and inform IBC members in writing as to which material is considered confidential.
6. Recommend to the VPAER qualified individuals who may serve on the IBC.
7. Ensure appropriate training of the Institutional Biosafety Committee members and PIs.[42]

C. IBC Members

1. The IBC voting members are responsible for the critical/expert analysis of protocols, any IBC business as directed by the IBC Chair, and the expert advice of biosafety-related material.
2. As directed by the IBC Chair (IV.B. *IBC Chair*), all IBC members, including ex-officio members and the VPAER, are trained on the following topics to include, but not limited to: Biosafety and Biosecurity, Animal Biosafety, NIH Recombinant DNA Guidelines, Emergency and Incident Response to Biohazard Spills and Releases.

D. Office of Research and Sponsored Programs

1. Review the procedures and activities of the IBC on an annual basis.
2. Recommends faculty members to the VPAER for appointment to the IBC.
3. Act as the liaison between WVSOM Senior Administration, research staff, and the IBC.
4. Administratively implements follow-up measures to be taken in response to IBC decisions made regarding significant or continuing non-compliance.

[42] NIH Guidelines; Section IV-B-1-h

5. Provide all confidential and secure database records and archival files of all registration documents, correspondence, membership minutes and decisions relating to IBC issues to the IBC and AVPRSP for maintenance.
6. Report any significant problems with or violations of the NIH Guidelines or any significant accidents or illnesses to the VPAER within 24 hours. Significant violations or incidents may include items such as:
   - Breach of containment for biohazardous agents, or a spill outside containment that cannot be easily and quickly cleaned up by one person.
   - Any worker exposure of biohazardous agents to mucus membranes, open skin, or inhalation of aerosols.
   - Any illness likely caused by biohazardous agents exposure.
   - Workers or PIs that willfully violate protocols or conduct work without prior IBC approval

   Note: PIs, workers, and other staff must report any of the above items to an IBC member and/or ORSP.
7. Conducts continuous quality improvement monitoring on all aspects of the IBC program (including the committee itself), to ensure institutional procedures regarding IBC review and approval, and protocol activities, are followed.
8. The ORSP Research Integrity and Compliance Administrator serves as a key contact between the ORSP and IBC and provides administrative support to the IBC Chair by assisting in the documentation of committee decisions, distribution of review materials, and the assignment of required training to protocol personnel as directed.

E. Vice President for Administration and External Relations (VPAER)

1. Establish an Institutional Biosafety Committee, as required in Section IV-B-1 of the NIH Guidelines, and as described in this document.
2. May act as the Authorized Institutional Official for accepting biohazardous agents or materials on campus.
3. As the signatory official, accepts responsibility for safety and risks for materials used.
4. Appoints all IBC members as outlined in the WVSOM Faculty Handbook.[43]
5. Ensure appropriate resources are available for training of the Institutional Biosafety Committee Chair.[44]
6. As per Section IV-B-1-j, report any significant problems, violations of the NIH guidelines, or any significant research-related accidents and illnesses to NIH OSP within thirty days.
7. As per Section IV-B-2-a-(3), file an annual report with NIH OSP, as described therein, if the WVSOM IBC is registered with NIH OSP.
8. Protocols that have been approved by the IBC may be subject to further review by the VPAER, who may overturn the IBC approval. However, the VPAER may not approve activities that have not been approved by the IBC. The VPAER has the authority to immediately halt any activity where there is evidence of noncompliance with WVSOM, State or Federal policy resulting in serious or unexpected risks to the individual, the public or the environment from recombinant or biohazardous materials. Such actions will be promptly reported to the IBC.

V. RESOURCES

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
https://osp.od.nih.gov/biotechnology/nih-guidelines/

[43] https://www.wvsom.edu/policies/faculty-handbook
[44] NIH Handbook; Section IV-B-1-h

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition:
https://www.cdc.gov/labs/BMBL.html

Workplace safety and Health:
http://www.cdc.gov/Workplace/

National Select Agent Registry:
http://www.selectagents.gov/

Bloodborne Pathogens Guidelines and Exposure Control Plan. West Virginia School of Osteopathic Medicine. July 2018. https://www.wvsom.edu/research/lab-safety

Bloodborne Pathogens and Needlestick Prevention. Occupational Safety and Health Administration. United States Department of Labor. https://www.osha.gov/SLTC/bloodbornepathogens/

This section below will be moved to the FAQ section on website
Appendix A – Faculty Resources

1. Evaluation of risk
    a. Facets to be considered in evaluating risk can be summed up as the 5 P's:
        i. Pathogen: This includes determining agent classification, routes of infection, infectious disease process, virulence, pathogenicity, and vector presence;
        ii. Personnel: Considerations include host immunity, immunization, attitudes toward safety, open wounds, and post-exposure prophylaxis;
        iii. Place: This refers to the laboratory facilities and concerns should include biosafety level requirements, aerosol risk, and restriction of access;
        iv. PPE (Personal Protective Equipment): This includes protection against aerosols, droplets, splatter, and sharps; and
        v. Procedures: Some points to consider are the existence and availability of laboratory SOPs, degree of adherence to SOPs by staff and supervisors, training, labelling of areas and equipment, routine inspections, and testing for new materials and equipment.
    b. Due consideration of the 5 P's will allow for a determination of biosafety level which will give the framework necessary for the development of a biosafety plan. This entails looking closely at the risk assessment triad of biological agent, host and personnel, and the environment to determine the degree of hazardous conditions when compared with a normal day-to-day human environment.
        i. Biosafety Level 1 (BSL-1): Research functioning in a BSL-1 environment is suitable for work by normally healthy adult humans and generally consists of working with well-defined, low-risk agents. Normal requirements for BSL-1 include general training for work with biological materials; sharps containers availability; decontamination as a routine process after work completion; sign posting for infectious agents; handwashing sinks available; effective pest management program; and updates and training.
        ii. Biosafety Level 2 (BSL-2): BSL-2 operations rise to the level of presenting a moderate hazard to personnel and the environment. Planning considerations differ in that personnel must have specific training and supervision when handling designated infectious agents; the laboratory must be restricted during research activity; and all work done with the potential for aerosols or splashes is conducted in Biological Safety Cabinets (BSCs) or other containment equipment. A lab-specific biosafety manual must be available; supervisor must ensure appropriate training and safety awareness by staff; autoclave availability in place; and medical surveillance and immunizations must be provided and explained as necessary.

Procedure Title: Institutional Biosafety Committee Procedures

Effective Date: March 25, 2021 Time: 12:01 a.m.

APPROVED BY:

Chair, Institutional Biosafety Committee:

Date: 3/18/21

Approving Administrator – Vice President for Administration and External Relations:

Date: 18 March 2021

Vice President for Legal & Governmental Affairs and General Counsel:

Date: 03-19-2021

President:

Date: 3/24/21

UPDATED: October 13, 2022