

**SUBJECT: Institutional Biosafety Committee Standard Operating Procedures**

**1. PURPOSE: Establish the Standard Operating Procedures for the Institutional Biosafety Committee (IBC).**

**2. DEFINITIONS:**

<b>ACOS/R</b>	Associate Chief of Staff for Research
<b>AO/R</b>	Administrative Officer for Research
<b>CV</b>	Curriculum vitae
<b>DMR</b>	Designated Member Review
<b>IBC</b>	Institutional Biosafety Committee
<b>NIH</b>	National Institute of Health
<b>PI</b>	Principal Investigator
<b>WOC</b>	Without Compensation Employee
<b>RDC</b>	Research and Development Committee
<b>SOP</b>	Standard Operating Procedure
<b>SRS</b>	Subcommittee on Research Safety
<b>rDNA</b>	Recombinant nucleic acids
<b>RPSS</b>	VA Form 10-0398 - Research Protocol Safety Survey
<b>RSSP</b>	Research Service Safety Program
<b>VA</b>	Veterans Affairs

**3. OVERVIEW:**

- a) The Institutional Biosafety Committee (IBC) is a subcommittee of the Research & Development Committee (RDC) under VHA Directive 1200.08.
- b) The IBC is specifically charged with managing projects involving non-exempt use of recombinant or synthetic nucleic acid molecules.
- c) Specific responsibilities of the IBC include:
  - i) Oversight of the use of recombinant and synthetic nucleic acid molecules in research laboratories to ensure compliance with all applicable rules and regulations.
  - ii) Oversight of the safety of personnel involved in research including ensuring compliance with all applicable rules and regulations.
  - iii) Reviewing and voting to approve or disapprove initial reviews, continuing reviews, and amendments for all protocols for which IBC is a subcommittee of record (studies involving non-exempt use of recombinant and synthetic nucleic acids).
  - iv) Coordination of appropriate safety training, safety inspections, accident reporting, and liaison activities with the SRS, RDC, and facility safety committees and officials.
  - v) Submitting information on IBC reviews to the SRS.

- vi) Reviewing the IBC Standard Operating Procedure (SOP), updating as necessary in compliance with National Institute of Health (NIH) guidelines on recombinant and synthetic nucleic acids.

#### 4. **PROCEDURES:**

- a) **Establishment:** The Minneapolis VA IBC is established as an internal committee under the SRS and charged with oversight of research involving non-exempt work with recombinant and synthetic nucleic acids at this facility.
- b) **Membership:** The IBC will consist of no fewer than 5 members, including 2 members who are not affiliated with the institution.
  - i) Members of the IBC are appointed in writing by the facility Director to serve on the IBC for terms of up to 3 years, with unlimited renewal at the discretion of the Director.
  - ii) The IBC Chair is appointed in writing by the facility Director for a term of up to three years, which may be renewed.
  - iii) Voting members of the IBC should include persons with expertise in:
    - 1) Experience and expertise in recombinant or synthetic nucleic acid molecule research and biosafety and physical containment.
    - 2) Knowledge of:
      - a. Institutional commitments and policies;
      - b. Applicable laws and NIH Guidelines;
      - c. Standards of professional conduct and practice;
      - d. Community attitudes;
      - e. Environmental considerations.
    - 3) The capability to assess the safety of research involving recombinant and synthetic nucleic acid molecules, and identify potential risks to public health and safety.
    - 4) Additional members may include lab personnel, PI's, and experts in safety and occupational medicine.
  - iv) Non-affiliated members of the IBC should have no relationship with the institution other than serving on the IBC.
  - v) New IBC Members will complete CITI Training “Biosafety Officer Training - Basic/Initial” and the IBC Chair will complete CITI Training “IBC Chair”
- c) **Review of Research Protocols:** The IBC is charged with reviewing projects that involve recombinant or synthetic nucleic acids, pathogens, or other biohazards. This review must include a full risk assessment, selection of proper containment, and assignment of any special provisions. The IBC may lower or raise containment provisions within the NIH Guidelines based on their risk assessment.
  - i) **Studies Exempt from IBC Review:** Studies that use recombinant and synthetic nucleic acids may be exempt from IBC review under certain conditions including:

- 1) Synthetic nucleic acids that:
    - a. Can neither replicate nor generate nucleic acids that can replicate in any living cell;
    - b. Do not introduce a stable genetic modification;
    - c. Do not produce a toxin that is lethal for vertebrates at an LD50 <100 ng/kg.
  - 2) Are not in organisms, cells, or viruses; and that have not been modified or manipulated to allow them to penetrate cellular membranes.
  - 3) Consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that is extant in nature.
  - 4) Composed entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related same species strain), or when transferred to another host by well-established physiological means.
  - 5) Consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related same species strain)
  - 6) Made entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent.
  - 7) Genomic DNA molecules that have acquired a transposable element, provided this element does not contain any recombinant and/or synthetic DNA.
  - 8) Do not present a significant risk to health or the environment.
- ii) **Administrative Review of Exempt Studies:** The IBC Chair, or another designated, qualified individual, may administratively review protocols to determine whether they may be exempt from IBC review.
- 1) Administrative review for exemption is conducted by the IBC Chair.
  - 2) The Chair will review the protocol (and accompanying VA Form 10-0398 Research Protocol Safety Survey (RPSS) and associated documents) for consistency with criteria for exemption.
  - 3) Should the reviewer agree that a protocol meets criteria for exemption from IBC oversight, they will record the protocol as “Acknowledged” in the electronic protocol management system.
  - 4) If the reviewer determines that a protocol does not meet criteria for exemption, the protocol will instead be referred to the full IBC committee for review.
- iii) **IBC Review of Research:** The IBC will review every research protocol covered by Section III-C of the NIH Guidelines (recombinant or synthetic nucleic acid molecule research involving research participants).
- 1) A Principal Investigator (PI) proposing use of recombinant and synthetic nucleic acids in research must submit for review a completed RPSS or an electronic equivalent. Protocols submitted

- without an RPSS, or submitted with an incomplete RPSS, will be returned to the PI for correction prior to IBC review.
- 2) Upon submission, the RPSS and accompanying documentation will be reviewed by the IBC Coordinator, who will determine the appropriate reviewer(s) for the protocol.
    - a. When multiple persons are assigned to review portions of a specific protocol, one individual (typically the IBC Chair) will serve as primary reviewer of the entire proposal, while secondary reviewers will focus on specific hazards only.
    - b. Review of specific hazards will be assigned to persons with expertise in that area.
  - 3) During IBC review of any new or amended protocol, the IBC will consider:
    - a. The biological and physical hazards associated with the research, e.g., administration, shedding;
    - b. The level of containment, laboratory procedures and practices, personal protective equipment, and training required for the research to be conducted safely;
    - c. The experience, expertise, and training of personnel involved;
    - d. The adequacy of the available laboratory space and resources; and
    - e. The status of the research, with respect to the NIH Guidelines.
  - iv) **Initial Review:** IBC review of all RPSS submissions that are subject to IBC oversight will occur at a convened IBC meeting in which a full quorum (a majority of the total voting membership) is present.
    - 1) All review will occur in real time either in person or virtually via videoconference or teleconference.
    - 2) IBC members who have conflicts of interest on a specific protocol may answer questions about the study, but will recuse themselves during deliberation and vote on the affected protocol. Recusal and verification of quorum must be documented in the IBC meeting minutes.
    - 3) If at any time quorum cannot be maintained, due to recusal or other reasons, no voting can occur until the quorum is restored.
    - 4) Approval of a protocol is obtained via majority vote of the voting members present. Voting on any IBC motion will only occur via real-time, in person or virtual process. The IBC may vote to:
      - a. Approve: Protocol is approved as submitted.
      - b. Approve with modifications: Protocol is provisionally approved, with final approval coming only after a Designated Member Review (DMR) verification that requested modifications have been added to the protocol.
      - c. Withhold approval: Should a majority vote not to approve a protocol, the IBC will provide a response to the PI explaining the reasons for this action.
    - 5) The PI and the SRS will be notified of the outcome of IBC review in writing.
      - a. For protocols in which changes were requested by the IBC, or where a reviewer requested clarification or additional information, such requests will be communicated to the PI in writing by the IBC Coordinator.
      - b. The outcome of the IBC review of the protocol will be communicated to the PI in writing and to the SRS via submission of the appropriate letter to the SRS Coordinator.

- v) **Amendments:** Any amendment that impacts the IBC relevant components of an approved protocol must be reviewed and approved by the SRS before proposed changes are implemented.
- 1) Amendments that are considered minor may be approved via DMR review. Examples of minor amendments include but are not limited to:
    - a. Changes that don't impact containment policies because they improve or don't impair the major phenotypic traits. PI must submit complete testing data on certified host-vector system modifications to a certified host-vector system require submission.
    - b. Reduction or removal of hazards previously approved by the IBC.
  - 2) Amendments that are not considered minor will be reviewed at a convened IBC meeting. Such amendments are reviewed following the same general procedure as outlined above for initial reviews. Amendments that require full IBC review include but are not limited to:
    - a. Adding new hazards;
    - b. Changes that impact containment policies;
    - c. Major host-vector system modifications.
  - 3) As with initial review, for amendments requiring review at a convened IBC meeting the IBC may vote to approve, to approve with modifications, or to withhold approval. Amendments that are approved with modifications may secure final approval via DMR.
  - 4) The outcome of the IBC review of the amendment will be communicated to the PI in writing and to the SRS via submission of the appropriate letter to the SRS Coordinator.
- vi) **Continuing Review:** Each approved IBC protocol will be reviewed once annually by the full IBC committee at a convened meeting.
- 1) The IBC will consider under this review any changes in personnel, in laboratory space, in containment protocols, and in host-vector systems.
  - 2) As with initial review, a protocol under continuing review approved with modifications may secure final approval via DMR.
- vii) **Designated Member Review:** DMR may be used in some cases to secure final IBC approval. At any point during the DMR process, any member of the IBC may request that the protocol be returned to the IBC for full committee review.
- 1) DMR may be used to secure final approval for:
    - a. Any initial review, amendment, or continuing review that was approved with modifications by the IBC at a convened meeting; or
    - b. Any minor amendment as defined by this SOP.
  - 2) DMR may only be conducted by a member of the IBC identified by the IBC Chair as having the appropriate expertise to make the determination.
  - 3) The designated reviewer may only approve or approve with modifications. If the reviewer instead feels that approval should be withheld, the protocol must be referred back to the IBC for full committee review.
  - 4) The outcome of any DMR review of a protocol, including date of approval, will be reported to the IBC at the next convened meeting and will be reported to the SRS.

## 5. **IBC MEETINGS:**

- a) **Meetings:** The IBC will hold convened meetings at least annually, either in person or via videoconference/teleconference. A quorum must be present for the meeting. If at any time quorum is lost, no business may be conducted until quorum is reestablished.
- b) **Agenda:** An agenda will be developed before each IBC meeting and distributed to IBC members via the electronic protocol management system at least 3 working days before the meeting whenever possible. The IBC agenda will include:
  - i) Any items requiring IBC action as well as a list of those items which have been resolved since the last convened meeting;
  - ii) A list of any initial reviews, amendments, or closures submitted for IBC vote;
  - iii) A list of any actions completed via DMR that have occurred since the last convened IBC meeting.
- c) **Minutes:** Minutes of all IBC meetings will be recorded and maintained for each IBC meeting.
  - i) The minutes will document:
    - 1) Place, date, and time of the meeting;
    - 2) Name of presiding officer (chairperson);
    - 3) The attendance record documenting presence of a quorum, including names of attendees and whether they are voting or non-voting members;
    - 4) Whether any alternate members are present, and if so, which member the alternate is replacing;
    - 5) Any recusals, including documentation that quorum was maintained for affected votes; and
    - 6) A complete record of all items of business brought before the IBC and the action taken, including all actions taken by the IBC itself.
  - ii) The IBC minutes will be reviewed and approved by the IBC via remote electronic voting. Final approved minutes will be maintained in the electronic protocol management system.
  - iii) Approved IBC minutes will be forwarded to the SRS for review. The SRS may review the minutes for content regarding committee functions, protocol review, education of members, and preparation of minutes. Recommendations for changes or improvements in IBC procedures may be made, but the SRS may not alter the IBC minutes.
- d) **Voting:** For each business item requiring a vote, the motion passed by the committee (approved, approved with modifications, approval withheld, as described above under Initial Review) will be recorded.
  - i) For any recusals, minutes must specify which members excused themselves from voting on each affected motion, and document whether quorum was maintained.
  - ii) Voting tabulations will be recorded in the meeting minutes.
- e) **Records:** Records will be archived as directed by National Archives and Records Administration Request for Records Disposition Authority DAA-0015-2015-0004.
  - i) IBC records, including agendas, meeting minutes, and copies of all submitted protocols, will be maintained in an electronic protocol management system provided by the VA Office of Research & Development. Any documents that cannot be maintained in this system will be stored electronically on the VA Research network storage array.

- ii) Protocols approved by the IBC will be kept for 6 fiscal years, and disapproved protocols or those withdrawn by the investigator will be retained for 3 fiscal years.
- iii) Files related to the ongoing operations of the IBC will be kept for 3 fiscal years (implementation records, including SOPs, policies, agreements with non-VA review committees, committee/subcommittee assessments and compliance) or 6 fiscal years (IBC records, including membership rosters, appointment letters, resumes, CVs, training records, meeting minutes and related documentation).

**6. REFERENCES:**

1. VHA Directive 1200.08 “Safety of Personnel and Security of Laboratories Involved in VA Research” (8 January 2021).  
[https://www.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub\\_Number](https://www.va.gov/vhapublications/publications.cfm?pub=1&order=asc&orderby=pub_Number)
2. FAQs on Institutional Biosafety Committee (IBC) Administration – April 2024.  
<https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy/faqs-on-institutional-biosafety-committee-ibc-administration-april-2024/>
3. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, April 2024, Section III. <https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2>

**7. IBC Committee Approval:** December 23, 2024

**8. RECISSIONS:** N/A

**EXPIRATION DATE:** N/A

**FOLLOW-UP RESPONSIBILITY:** Institutional Biosafety Committees (IBC)