



## INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) CHARTER

### I. Purpose

Institutions that receive support from the National Institutes of Health (NIH) are required, by the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines), to establish and register an Institutional Biosafety Committee (IBC).

Virginia Commonwealth University's (VCU) Institutional Biosafety Committee (IBC) is required by the NIH Guidelines to review research or other approved work with recombinant or synthetic nucleic acid molecules. VCU's Biosafety Office (BSO) has delegated authority from VCU's Vice President for Research and Innovation (VPRI) and VCU's Assistant Vice President for Safety and Risk Management (AVP for SRM) to define other research and work, including infectious agents, that must be submitted to VCU's IBC for review.

Provisions of this charter shall apply to all research and production projects conducted in VCU facilities or property, including all rental or leased facilities or properties, as well as to all such projects carried out by VCU staff (temporary or full time), students or visitors on behalf of VCU.

### II. Responsibilities

#### Institutional Biosafety Committee (IBC)

1. Review research or other work with recombinant or synthetic nucleic acid molecules and other research or work defined by VCU's BSO as requiring IBC review.
2. VCU's BSO is responsible for reviewing registrations submitted to the IBC that do not fall under the NIH Guidelines. The BSO may request a review, by the IBC, on specific safety questions associated with those registrations.
3. Report any violation of the NIH Guidelines to the NIH Office of Science Policy (OSP) and the VPRI and AVP for SRM within 30 days.
4. Periodically review previous IBC approved research.
5. Investigate potential violations of approved IBC protocols and/or NIH Guidelines.
6. Recommend sanctions to the VPRI and the AVP for SRM, under the Safety and Risk Management policy, for any individual who has violated the terms of an approved protocol, conducted projects subject to its authority without gaining appropriate IBC approval, or otherwise violated any provision of applicable federal, state, and local regulations and guidelines, or institutional policies regarding subjects under its purview.

7. Train IBC members with respect to all applicable federal, state, and local regulations and internal SOPs.
8. Perform an annual review of the IBC's compliance with the NIH Guidelines using assessment tools from NIH OSP, and submit the findings to the OVPRI and the AVP for SRM.
9. VCU's IBC is responsible for compliance with the NIH's "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC) (September 2014)." A standing sub-committee, the Institutional Review Entity (IRE), is responsible for reviewing any research or work conducted at, or on behalf of VCU that meets the DURC definition.

### **Biological Safety Office (BSO)**

1. Prepare a report of all lab related accidents involving IBC registrations and submit the report annually to the IBC.
2. Manage the Biosafety Program and support implementation of IBC policies and procedures through training, facility inspections, and communication of Biosafety Program and related regulatory requirements.
3. Review registrations submitted the IBC that do not fall under the NIH Guidelines, which may include requesting the review of specific safety questions associated with those registrations.
4. Recommend the appointment of the IBC Chair, Vice-Chair and committee members to the VPRI and the AVP for SRM as needed.
5. Perform annual inspections of any laboratories registered with the IBC for compliance with NIH Guidelines.
6. Screen research protocols submitted by PIs and make recommendations to the IBC.
7. Monitor Federal, Commonwealth of Virginia, and local regulatory trends regarding the scope of IBC authority, and communicate any changes to the IBC.
8. Direct the content, preparation, and submission of annual reports to NIH.

### **IBC Coordinator**

1. Serve as departmental point of contact on matters relating to IBC processes and procedures.
2. Intake all registration applications including initial registrations, amendments, and renewals.
3. Conduct a pre-review of all protocols to ensure overall protocol completeness and to appropriately assign protocols to reviewers with adequate expertise.
4. Prepare meeting agendas and communicate all related protocol materials required for IRB member review.
5. Maintain electronic BioRAFT Registration forms and applications for IBC review.
6. Maintain and secure Microsoft Word form registrations.
7. Maintain documents to assure IBC registrations are up-to-date.
8. Manage the content of the IBC website for accuracy and completeness.
9. At the direction of the BSO, submit annual reports to NIH.

10. Prepare reminders for training updates and scheduling of meetings.
11. Ensure all IBC members are adequately trained and documentation is kept appropriately.

### **Principal Investigator (PI)**

1. Maintain primary responsibility and accountability to facilitate appropriate conduct of research or other approved work with recombinant or synthetic nucleic acid molecules.
2. Must be available to devote adequate time and attention to the research to ensure its responsible conduct in compliance with *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules*.
3. Ensure that there are adequate resources to carry out the research safely.
4. Accurately disclose proposed research and procedures through the appropriate submission process via BioRaft or Microsoft Word form registration.
5. Ensure adequate training and oversight of research and/or laboratory personnel.
6. Submit reports and research modifications in a timely manner. Reports include, but are not limited to, incident reports, safety reports, and adverse event reports.

### **III. Membership**

The VPRI selects the IBC Chair via formal appointment letter for a three-year term of service or an alternative time period, as deemed necessary. The VPRI, with input from the AVP for SRM and VCU's BSO, appoints IBC members to fill the positions listed in the voting. IBC members receive a formal appointment letter from the VPRI for no more than three-year terms of service. To remain in good standing, a member must attend a majority of IBC meetings annually and complete appropriate training requirements. Appointments shall be made to ensure staggered periodic replacement and continuity of the IBC.

- a) Individuals holding the following positions or titles at VCU shall be appointed to the IBC as voting or alternative voting members:
  - i) Chairman
  - ii) Vice Chairman
  - iii) Attending Veterinarian (or designee from VCU's Division of Animal Resources)
  - iv) Biosafety Officer
  - v) Assistant Biosafety Officer
  - vi) Practicing Scientist (Biochemistry)
  - vii) Practicing Scientist (Virology)
  - viii) Practicing Scientist (Plants)
  - ix) Public Member
  - x) Public Member
  - xi) Designated voting Office of Research representative
  - xii) Alternative Voting Members:
    - (1) Practicing Scientist
    - (2) Safety Expert
    - (3) Compliance Expert

b) Ad-Hoc Experts as needed

**Alternate Membership:**

1. Individuals may be appointed to the IBC as alternates for a specific IBC member or multiple members.
2. Alternate members must be discipline matched and have similar expertise, including the same scientific or non-scientific status as the voting members they are assigned to replace.
3. Alternate members may vote in the absence of the member they are assigned to as an alternate.
4. If assigned to multiple members, alternate may only represent a single vote and only count once towards quorum.

Voting members may not be assigned a review and must recuse themselves from any vote on a research protocol in which they have been or will be participating, or in which they have a direct or perceived conflict of interest.

**IV. IBC Meeting Procedures**

1. The IBC shall meet monthly and additionally at the call of the Chair.
2. The Chair, or designee, presides over all meetings and oversees all IBC activities.
3. IBC members are expected to notify the IBC Coordinator within one week of a meeting if they are unable to attend the meeting.
4. The IBC Coordinator, with input from the BSO and IBC Chair, shall appoint a reviewer(s) for each MUA determined to be nonexempt by the BSO.
5. A quorum shall consist of a simple majority of members eligible to vote on a specific protocol, with a minimum of one member being a practicing scientist.
6. To take action, a quorum must be present in person, telephone or video conferencing. Decisions and registration approvals are based on a majority vote of voting members present at the time a vote is taken.
7. Additional subcommittees consisting of at least three members may be formed to address specific issues. The Chair will select subcommittee members (including the VCU Biosafety Officer) with experience relevant to the specific issues.

**V. Amendments and Review**

1. The IBC Charter shall be reviewed by the IBC annually.
2. Amendments to the IBC Charter may be proposed by the IBC to the VPRI and the AVP for SRM for approval.

**VI. Effective Date**

IBC Charter takes effect immediately upon receipt of the signatures listed below.

**VII. Approval**



**Vice President for Research and Innovation**

4/8/19

**Date**



**Assistant Vice President for Safety and Risk Management**

23 APR 2019

**Date**