University of Virginia

Charge of the Institutional Biosafety Committee

Authorization: The University of Virginia shall have an Institutional Biosafety Committee established under the authority of the Office of the Vice President for Research.

Committee Composition: The Institutional Biosafety Committee shall consist of at least 10 voting members appointed by the Vice President for Research (VPR). Membership will generally consist of faculty members with expertise in recombinant DNA technology, microbial pathology, virology and viral vectors, biosafety, biotoxins, transgenic plants, transgenic animals or biotechnology. Non-faculty members such as administrative representatives, laboratory staff or students may also be appointed in consultation with the IBC Chairperson.

Committee membership must also include the University Biological Safety Officer, a representative from the Center for Comparative Medicine with expertise in animal containment principles, and at least two community members who are not affiliated with the University.

A member with expertise in plant, plant pathogen, or plant pest containment principles is required for review of recombinant DNA experimentation involving plants as determined by the IBC Chairperson. The need for expertise in human gene therapy through membership or consultation shall be determined by the IBC Chairperson.

The IBC Chairperson may establish focused subcommittees at his or her discretion, invite subject matter experts to consult, provide input or reports on a given topic, and make membership recommendations to the VPR.

Members are appointed for renewable three year terms.

General Charge: The Institutional Biosafety Committee (IBC) is a standing committee responsible for reviewing all proposed University research and teaching activities conducted by faculty, staff, students and/or visiting scientists and ensuring that they are aware of the responsibility to register the use of biological agents or activities as described below:

a) Microorganisms;
b) Activities subject to the NIH Guidelines for Research Involving Recombinant DNA or Synthetic Nucleic Acid Molecules (*NIH Guidelines*);
c) Materials derived from human and nonhuman primates;
d) Biological Toxins with an LD_{50} of less than 100 micrograms per kilogram of body weight in vertebrates;
e) Select agents or toxins subject to 42 CFR Part 73, 9 CFR Part 121, or 7 CFR Part 331;
f) Proposed research subject to the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern.

The purpose of these reviews is to ensure that all activities involving biological agents and the facilities used to conduct such work are in compliance with all external regulations, and applicable University policies. The committee will function to ensure that investigators handle biological agents in a safe and responsible manner, and meet criteria as described by the NIH

Guidelines for recombinant DNA research (specifically those defined in section IV-B-2); the CDC/NIH publication Biosafety in the Microbiological and Biomedical Laboratories; applicable regulations defined by the Virginia Department of Environmental Quality; the OSHA Bloodborne Pathogens Standard; HHS and USDA final rules for the possession, use, and transfer of select agents and toxins; and other applicable requirements.

Foremost, the IBC's objective shall be to ensure that such activities meet the standards of good biological safety practice emphasizing protection of personnel, the public and the environment. To this end, the IBC shall assist principal investigators in meeting their responsibilities, impose requirements, review and approve policies, proposals, procedures, programs, and facilities pursuant to the safe and legally compliant use of biological agents.

Meetings: The Institutional Biosafety Committee shall gather at a convened meeting at least once per month to review submissions and address other business items. The IBC Chair will ensure that any and all members recuse themselves from committee business if they are involved in the research project under review, or have a direct conflict of interest, except to provide specific information requested by the committee.

Meeting schedules, submission deadlines, and committee membership must be made readily available to the University community. Meeting agendas, minutes, documentation, and other meeting and coordination efforts will be arranged by the IBC Coordinator. At least fifty-one percent of the voting membership is necessary to establish a quorum for conducting business. Members of the University community and the general public may attend meetings so long as they are not disruptive to committee business and protection of proprietary or privacy interests are not breached.

Support: The VPR shall provide resources necessary to support IBC operations. This may include staffing, database services, support for member education, clerical equipment or materials, and other resources necessary to support committee operations.

The Biological Safety Officer, as a member of the Office of Environmental Health and Safety (EHS), will serve as a functional arm of the IBC and manage day-to-day operations in conjunction with IBC administrative staff and EHS staff. Services include providing technical expertise, periodic inspections to ensure that laboratory standards are rigorously followed, reporting of incidents or violations to the committee, development of emergency plans for spills or contamination, advice on laboratory biosecurity, recommendations for improvement, regulatory updates, and other support as needed.

Appeals: In cases of dispute with respect to procedures or decisions of the IBC, appeals should be made to the IBC in writing or in person. Appeals unresolved through IBC channels may be subsequently presented to the VPR for resolution.

Sanctions and Enforcement: The IBC shall investigate suspected or alleged violations of protocols, external regulations, or University policies that involve biological agents. If violations are insufficiently resolved through normal channels of communications with the Principal Investigator, the Department Chairperson will be notified of the violation and a timeline for

resolution will be established. Matters that remain unresolved will be forwarded to the relevant school dean and VPR for resolution. In matters that are deemed immediately dangerous to life and health, the IBC may immediately suspend research involving biological agents. In such extreme cases, and after consultation with the VPR, the IBC may also authorize access restriction, or removal of personnel.

Accidents or Breach of Containment:
Any accident or serious breach of containment involving biological agents shall be reviewed by the IBC. The IBC may recommend or require probationary approval and specific actions such as training and additional inspections to the Principal Investigator. Additional sanctions may be delivered as described in the sanctions and enforcement section of this document.

Any accident or serious breach of containment involving biological agents that leads to significant personal injury shall be reported to the VPR. Certain incidents, as described in the *NIH Guidelines*, must be reported to the NIH Office of Science Policy (OSP). The IBC chair and the Biosafety Officer will jointly file these reports.

Reporting: The committee reports administratively to the VPR through the Associate Vice President for Research Compliance. The committee is responsible for forwarding an annual written report to:

1) The VPR which describes the committee's activities and deliberations during the previous year. The report should include a roster of all IBC members and their participation, description of committee accomplishments, regulatory compliance, new or modified policies, areas in need of improvement, and other items as appropriate.
2) The NIH/OSP which includes; a roster of all IBC members clearly indicating the Chair, contact person, Biological Safety Officer, plant expert (if applicable), animal expert, human gene therapy expertise or ad hoc consultant (if applicable); and biographical sketches of all IBC members (including community members).

Approved:

25 Oct 2017

David Hudson, PhD — Date

Senior Associate VP for Research
Research Integrity Officer