SEC-012 Biosafety

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Status Final

Last Revised Tuesday, January 31, 2023

Policy Type University

Contact Office
Environmental Health and Safety

Oversight Executive
Vice President for Research

Applies To
Academic Division The Medical Center

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Reason for Policy

To protect University faculty, staff, students, visitors, and the general public from biological agents used by the University of Virginia.

Definition of Terms

Biological Agents

This includes:

1. **Microorganisms**;
2. **Human and non-human primate derived materials** which may contain human pathogens (e.g. blood, fluids, tissues, organs, primary and established cell lines, etc.);
3. **Biotoxins** with an LD50 of less than 100 micrograms per kilogram of body weight in vertebrates;
4. **Recombinant or Synthetic Nucleic Acid Molecule** activities as described in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (includes human gene transfer); and
5. **Select Agents or Toxins** as defined by CDC (42 CFR 73) or USDA (9 CFR 121 or 7 CFR 331).

Policy Statement

The University of Virginia will comply with all applicable federal, state, and local regulations which apply to the possession, manipulation, and disposal of biological agents. Additionally, consensus biosafety guidelines such as those from the National Institutes of Health, Centers for Disease Control, and other organizations will be applied as appropriate to protect personnel and the environment from potentially adverse exposures to biological agents.

All Principal Investigators or faculty who possess or use biological agents must register the possession and use of biological agents with the University of Virginia Institutional Biosafety Committee (IBC). Investigators and

faculty are authorized to proceed with the proposed activities only after obtaining IBC approval. Principal Investigators and faculty are responsible for ensuring that their practices, equipment, and facilities do not jeopardize the health and well-being of themselves, their personnel, or the general public. The IBC and Environmental Health and Safety provide consultation and assistance to Principal Investigators and faculty in this regard.

Registration and Approval Mechanics:
All Principal Investigators and faculty who possess or use biological agents are required to complete an IBC registration document. Those investigators or faculty who indicate regulated status will have their submission document reviewed at a convened IBC meeting.

1. New registrants are contacted to schedule a laboratory inspection, which includes evaluation of appropriate work practices, containment, signs and labeling, an acceptable biosafety manual, and other factors. Completion of a satisfactory inspection, submission of requested records, forms, or other documentation results in assignment of an approval number and an acceptance letter, at which time the Principal Investigator or faculty member is authorized to proceed with the proposed activities.

2. Once initial IBC approval has been granted, Principal Investigators and faculty must submit registration modifications for review and approval prior to acquiring new biological agents, adding work or storage areas, or engaging in new procedures. The IBC's disposition of proposed registration modifications will depend largely upon the nature of the modification, and may result in: immediate approval, request for additional information or inspection, or disapproval. Principal Investigators and faculty who have not submitted modifications in the previous one-year period are required to review the previous online registration submission to confirm its accuracy.

Compliance with Policy:
Failure to comply with the requirements of this policy may result in disciplinary action up to and including termination and expulsion in accordance with relevant University policies. Non-compliance may be subject to enforcement and penalties as defined by Code of Virginia § 40.1-51.22 and § 40.1-51.39. Non-compliance with Occupational Safety and Health Administration (OSHA) requirements may be subject to enforcement and penalties as defined by the United States Department of Labor (DOL) Federal Civil Penalties. Non-compliance with NIH Guidelines may jeopardize federally funded research. The Inspector General of the Department of Health and Human Services is delegated authority to conduct investigations and to impose civil money penalties against any individual or entity in accordance with regulations for violations of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188). The delegation of authority includes all powers contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).Investigators/faculty who possess or use biological agents without appropriate IBC approval are subject to suspension of research funding, and laboratory closure at the discretion of the IBC, Institutional Biosafety Officer, or Responsible Official (per 42 CFR Part 73). The Office of Sponsored Programs will not release external funding for projects involving biological agents without evidence of IBC approval.

Questions about this policy should be directed to Environmental Health and Safety.

Major Category Safety, Security and Environmental Quality

Next Scheduled Review Saturday, January 31, 2026

Revision History Confirmed 1/31/23; Updated 11/11/19; 7/21/11.

Applies To Text
Academic Division and the Medical Center.

Supercedes Policy Text
XIV.D.1: Biosafety.

Last modified February 5, 2024 - 3:11pm

Approved By Policy Review Committee

Approved Date June 30, 2005 - 12:00pm