Virginia Tech Recombinant and Synthetic Nucleic Acid and Biohazard Research Policy

No. 13030

Policy Effective Date:
1/28/2014

Last Revision Date:
5/5/2025

Policy Owner:
Dan Sui

Policy Author:
(Contact Person)
Regina Allen

Affected Parties:
Undergraduate
Graduate
Faculty
Staff
Other

1.0 Purpose
2.0 Policy and Principles
3.0 Oversight
4.0 Responsibilities of Researchers and Instructors
5.0 Definitions
6.0 References
7.0 Approval and Revisions

1.0 Purpose

This policy establishes requirements for the safe, secure, and compliant use of recombinant or synthetic nucleic acid molecules and other biohazardous materials. These requirements are intended to maintain compliance with federal and state laws and regulations to protect university personnel, the public, and the environment.

2.0 Policy and Principles

It is recognized that use of potentially biohazardous materials and organisms containing recombinant or synthetic nucleic acid molecules is necessary in many research and teaching laboratories at Virginia Tech. To implement the compliant handling of these organisms, Virginia Tech requires that all research and instructional activities involving recombinant or synthetic nucleic acid molecules (rsNA) or biohazardous materials conducted at Virginia Tech shall be conducted in accordance with federal and state laws and regulations.

Virginia Tech's commitment is guided by the requirements described in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* and other applicable federal and state laws and regulations. To oversee compliance with the *NIH Guidelines* and other federal and state laws and regulations, Virginia Tech has established an Institutional Biosafety Committee (IBC) that is supported by the Institutional Biosafety Committee Program (IBCP). The IBC is responsible for implementing compliance of laws and regulations for the use of biohazardous agents at all Virginia Tech facilities.

2.1 Applicability of Policy

This policy, and its amendments and additions, applies to all research and instructional activities that involve the use of any biohazardous agents, including recombinant or synthetic nucleic acid molecules, regardless of the funding sources involved.

3.0 Oversight

3.1 Virginia Tech, The Institution

Virginia Tech follows the *NIH Guidelines* and other federal and state laws and regulations for the compliant use of biohazardous agents.

3.2 Senior Vice President for Research and Innovation

The Senior Vice President for Research and Innovation serves as the Institutional Official (IO) for the university and is responsible for oversight of compliance for activities involving the handling and use of recombinant or synthetic nucleic acid molecules and other biohazardous materials.

The IO will specify any additional responsibilities necessary for the function and operation of the institutional biosafety committee program to advise in the compliant use of biohazardous materials and will delegate these responsibilities to the appropriate individuals.

The IO will appoint members to the Institutional Biosafety Committee.

3.3 Division of Scholarly Integrity and Research Compliance

The division of Scholarly Integrity and Research Compliance (SIRC) is an administrative unit directed by the Associate Vice President (AVP) for Research and Innovation. SIRC has responsibility for the implementation of Virginia Tech policies and procedures for compliance of research and instructional activities involving biohazardous materials.

3.4 Institutional Biosafety Committee Program

The Institutional Biosafety Committee Program (IBCP) is an administrative unit within SIRC and is responsible for administrative support to the IBC. The IBCP is charged with supporting the IBC in fulfilling their responsibility for implementing compliance of research and instructional activities with federal and state laws and regulations for the use of recombinant or synthetic nucleic acid molecules and other biohazardous agents at Virginia Tech facilities.

3.5 Institutional Biosafety Committee (IBC)

The Virginia Tech IBC is composed of a minimum of 5 members. On behalf of Virginia Tech, the IBC is responsible for:

(i) Reviewing and approving activities involving the use of recombinant or synthetic nucleic acid molecules or other potentially biohazardous material conducted at university facilities for compliance with the *NIH Guidelines* and other federal and state laws and regulations

(ii) Periodically re-reviewing applicable work conducted at the institution to implement compliance with the *NIH Guidelines* and other federal and state laws and regulations

(iii) Following all other requirements of the IBC set forth by the *NIH Guidelines*

(iv) Following federal and state laws and regulations, as applicable and required

(v) Reporting any significant problems with or violations of the *NIH Guidelines* and federal and state laws and regulations and any significant research-related accidents or illnesses to the appropriate institutional officials and federal and state agencies, as applicable and required

(vi) Performing such other functions as delegated to the IBC by the university

The IBC has the authority to approve, require modifications, disapprove, or halt research and instructional activities that fall within its jurisdiction as specified by the *NIH Guidelines* and federal and state laws and regulations. The IBC has the authority to require appropriate training of faculty and students and to prohibit individuals who have not completed training from working under an approved protocol.

4.0 Responsibilities of Researchers and Instructors

Researchers, instructors, staff, and students participating in activities involving the use of recombinant or synthetic nucleic acid molecules or other biohazardous materials, are responsible for being familiar with *NIH Guidelines,* state and federal laws and regulations, and other related university policies for the use of biohazards. The

principal investigator or instructor is responsible for the conduct of the research and instructional activities. The principal investigator or instructor is required to:

(vii) Complete the required IBC training for the specific activities conducted before handling biohazardous materials and maintain competency by completing required refresher trainings as applicable.

(viii) Submit proposed research activities to the IBCP office for review prior to the initiation of any activities.

(ix) Confirm that no activities are initiated or modified prior to IBC review and approval.

(x) Report any significant problems, loss of containment, violations of the *NIH Guidelines* or federal or state laws and regulations, or any significant accidents and illnesses, to the IBC and other appropriate departments and authorities.

(xi) Confirm that they are adequately trained in good microbiological techniques, and that they have appropriately trained staff and students in those techniques. All training records must be maintained by the principal investigator or instructor.

(xii) Follow all IBC approved plans for handling accidental spills and personnel contamination.

(xiii) Comply with university and federal and state shipping requirements for recombinant or synthetic nucleic acid molecules or other biohazardous materials.

(xiv) Acquire permits for obtaining and transporting organisms and materials as required by applicable federal and state laws and regulations.

(xv) Communicate any proposed changes, or any problem encountered, to the IBC.

(xvi) Supervise the safety performance of staff and students to implement use of required safety practices and techniques.

(xvii) Correcting work errors and conditions that may result in the release of recombinant or synthetic nucleic acid molecule materials or other biohazards, or exposure of lab personnel to recombinant or synthetic nucleic acid molecule materials or other biohazardous agents or toxins.

(xviii) Regularly check, and correct as necessary, the integrity of the physical and biological containment equipment

(xix) Be in compliance with IBC approved protocols.

(xx) Be in compliance with Environmental Health and Safety policies and other university policies, regarding the use of biohazardous agents.

(xxi) If leaving the university before completing an approved protocol, in conjunction with their department head or institute director, identify a new principal investigator for the protocol.

(xxii) Close out the protocol when activities are completed.

5.0 Definitions

Biohazardous Materials – Infectious biological or synthetic agents, biologically derived materials and toxins that present a risk or potential risk to the health of humans, animals, or plants either directly through exposure or infection or indirectly through damage to the environment. Categories of potentially infectious biological materials may include the following:

- human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions)
- toxins of biological origin
- human and non-human primate cells and unfixed tissues
- genetically engineered organisms, plants, animals, and veterinary biologics
- select agents and toxins
- infected animals and plants, including tissues
- recombinant and synthetic nucleic acid molecules
- any agent or material requiring BSL-2 containment or higher, even if not infectious to humans

BMBL – The CDC/NIH handbook, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* provides a code of practice for biosafety, addressing the safe handling and containment of infectious microorganisms and hazardous biological materials. It is used to assess containment practices and personal protective equipment required for activities proposed in an IBC protocol.

IBC Approval – An IBC approval is the determination of the IBC that the research or instructional activities have been reviewed and may be conducted within the constraints set forth by the IBC and by other institutional and federal and state requirements.

IBC Research or Teaching Protocol – Information provided by the principal investigator to the IBCP that describes the activities that will be performed using biohazardous materials, including recombinant or synthetic nucleic acid molecules and the cells, organisms, and viruses containing such molecules, and the facilities and equipment that will be used to contain the organisms and other experimental materials.

Institutional Official - Institutional official (IO) is the term used by Virginia Tech to refer to the individual who is authorized to act for the institution and, on behalf of the institution, implements the terms of the *NIH Guidelines*.

NIH Guidelines – The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* specify the practices for constructing and handling of: (i) recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (iii) cells, organisms, and viruses containing such molecules. The guidelines are applicable to all recombinant or synthetic nucleic acid research within the United States or its territories, regardless of the source of funding for the research.

6.0 References

Virginia Tech IBC website:
https://www.research.vt.edu/ibc/index.html

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition
https://www.cdc.gov/labs/BMBL.html

Department of Agriculture related Regulations
7 CFR Part 330: https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-330
7 CFR Part 340.4: https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-340/section-340.4
9 CFR Part 122: https://www.ecfr.gov/current/title-9/chapter-I/subchapter-E/part-122

Department of Commerce, 15 CFR 774 Supplement 1:
https://www.ecfr.gov/current/title-15/subtitle-B/chapter-VII/subchapter-C/part-774

Department of Health and Human Services, 42 CFR Part 71, including Part 71.54:
https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-71

Department of Labor, 29 CFR Part 1910.1030:
https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030

Department of State, 22 CFR Parts 120-130:
https://www.pmddtc.state.gov/ddtc_public/ddtc_public?id=ddtc_kb_article_page&sys_id=24d528fddbfc930044f9ff621f961987

Department of Transportation, 49 CFR Parts 100-185:
https://www.phmsa.dot.gov/standards-rulemaking/hazmat/hazardous-materials-regulations

Federal Select Agent Program Regulations, 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73:
https://www.selectagents.gov/regulations/index.htm

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules:
https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/

Virginia Department of Environmental Quality, 9 VAC 20-121:
https://law.lis.virginia.gov/admincode/title9/agency20/

7.0 Approval and Revisions

Approved January 28, 2014 by Virginia Tech Institutional Biosafety Committee (IBC)
Approved January 29, 2014 by Vice President for Research, Robert W. Walters.
Approved May 15, 2014 by University President, Charles W. Steger.

- Revision 1
  - Technical revision and title changes throughout
  - Included provision for in-person annual review meetings in section 2.2.2.2

  Policy review and technical changes recommended by the Virginia Tech Institutional Biosafety Committee and by IBC Administrator, Regina Allen on November 12, 2019.

  Approved January 7, 2020 by Vice President for Policy and Governance, Kim O'Rourke.

- Revision 2
  This policy was completely revised to align with the May 6, 2024 United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential, effective May 6, 2025.

  Approved May 5, 2025 by Senior Vice President for Research and Innovation, Dan Sui.