Governance of the Virginia Tech Institutional Biosafety Committee (IBC)

I. Introduction:

This document serves as the Charter of the Virginia Tech Institutional Biosafety Committee. Sections in parentheses denote applicable *NIH Guidelines* sections.

The requirement for formation and operation of an IBC, including the qualifications and appointment of its membership, and its duties and responsibilities, is described and mandated by the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* (IV-B-1-b, IV-B-2-b) and Virginia Tech Research Policy 13030.

Recombinant and synthetic nucleic acid molecules are referred to as rsNA henceforth.

The purpose of the IBC is to

1. ensure the safe and compliant use of biohazardous materials by the university community in research and teaching activities which includes (IV-B-1-g):
   - Recombinant and synthetic nucleic acid (rsNA) molecules;
   - Genetically modified and/or genetically engineered microorganisms, animals and plants;
   - Risk Group 2 (ABSL2/BSL2) and Risk Group 3 (ABSL3/BSL3) agents;
   - Toxins of biological origin;
   - Manipulation or culturing of human, non-human primate, and mammalian blood, blood products, cells, and unfixed tissue;
   - Animal/plant pathogens and products, specific genetically engineered organisms and veterinary biologics;
   - Select agents and toxins; and
   - Related biosafety issues as referred by the IACUC and IRB (IV-B-1-f, NIH OSP recommended).
2. advise other health and safety oversight committees on biosafety issues.
3. serve as an enforcement committee for non-regulated biosafety areas.
4. work to meet the requirements of federal, state, and local regulations, university policies, and standards of practice, as applicable.
5. minimize the occurrence of accidents and illnesses involving biohazards through review and oversight.

II. Key Individuals Specified in the *NIH Guidelines*

There are 7 required roles that the IBC roster must include, if applicable to the research conducted at the institution. Additionally, there are 3 roles that the NIH Office of Science Policy (NIH OSP) recommends are included on the IBC roster.

The IBC roster includes constituent voting members and *ex officio* voting members.

II.A Required Membership

The IBC NIH roster (on NIH RMS system) must include the following roles to be annually approved.

II.A. 1 IBC Contact; can be non-voting (IV-B-2-a-(3))

1. The IBC Program Director serves as the non-voting IBC contact for Virginia Tech.
2. Role and responsibilities:
   - serves as a contact for the NIH OSP to provide news, updates, and approvals;
   - submits the annual update of the IBC roster to the NIH OSP; and
   - submits any changes to the IBC roster to the NIH OSP as needed;

II.A.2 IBC Chair (IV-B-2-a-(3))

1. manage scheduled and emergency IBC meetings, ensuring that a quorum is present so that official business can be conducted;
2. approve agenda for upcoming meetings;
3. appoint IBC subcommittees as needed;
4. communicate IBC needs, concerns, and questions to the IO;
5. assign IBC members for Primary Review of Full Committee protocols;
6. review and approve Exempt protocols;
7. provide final confirmation if protocols require full committee review or exempt review; and
8. interact with the IBC Program staff as needed.
9. meet with the AVP for SIRC monthly.

II.A.3 Biosafety Officer (IV-B-1-c, IV-B-2-a-(1), IV-B-2-a-(2), IV-B-3)

1. reviews protocols involving the use of rsNA large cultures (>10 liters)
2. reviews protocols involving the use of rsNA at BSL-3 containment
3. Periodic inspections of facilities to ensure that laboratory standards are rigorously followed;
4. reporting to the IBC and the IO any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses;
5. submits incident report to the NIH OSP;
6. developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecule research;
7. providing advice to the IBC on laboratory security; and
8. providing technical advice to Principal Investigators and the IBC on research safety procedures.

II.A.4 Animal containment practices expert (IV-B-1-e, IV-B-2-a-(1), IV-B-5)

The Virginia Tech IBC has two positions to fill this requirement. One position is *ex* officio and is filled by the Attending Veterinarian (AV) for Virginia Tech (VT). The second position is a Faculty member.

1. Roles and responsibilities

- review protocols involving the use of animals that are applicable to Appendix Q of the *NIH Guidelines*;
- provide guidance on appropriate containment for such experiments; and
- ensure that the research meets the requirements specified in Appendix Q of the *NIH Guidelines*.

II.A.5 Plant containment practices expert (IV-B-1-d, IV-B-2-a-(1), IV-B-4)

1. Roles and responsibilities
   - review protocols involving the use of animals that are applicable to Appendix P of the *NIH Guidelines*;
   - provide guidance on appropriate containment for such experiments; and
   - ensure that the research meets the requirements specified in Appendix P of the *NIH Guidelines*.

II.A.6 Community Members (IV-B-2-a-(1))

1. Roles and responsibilities
   - represent the interest of the surrounding community with respect to health and protection of the environment; and
   - shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee).

II.A.7 Human Gene Transfer Expert (IV-B-1-f, IV-B-2-a-(1), IV-B-5)

If Virginia Tech participates in or sponsors research involving rsNA involving human subjects, the IBC will include a minimum of one member (faculty or *ad hoc*) with expertise and training in human gene transfer experiments and in all aspects of Appendix M of the *NIH Guidelines*.

II.B NIH OSP Recommended Membership (IV-B-2-a-(2))

II.B.1 Laboratory techniques/management

The Virginia Tech IBC member roster includes at least one voting member who serves a faculty or staff position as a laboratory technician, laboratory manager and/or facility manager.

II.B.2 Institutional commitments and policies, and standards of professional conduct and practice

The Associate Vice President for Scholarly Integrity and Research Compliance acts as a consultant for the IBC, when requested, in matters related to institutional commitments and policies, applicable law, standards of professional conduct and practice, and community attitudes. The IBC Program Director attends all meetings and acts as a consultant, with support from the VP for Scholarly Integrity and Research Compliance and the IO (VP for Research and Innovation). The consultants act as resources for the IBC members and are not members of the IBC.

II.B.3 Biological safety

The Virginia Tech IBC member roster includes the Assistant Vice President of Environmental Health and Safety as an *ex officio* voting member to provide guidance on environmental health and safety.

III. IBC Membership Procedures

III.A Membership

In accordance with the *NIH Guidelines*, the IBC is comprised of no fewer than five members, so selected that they collectively have experience and expertise in rsNA technology, biological safety, physical containment, and technical and practical knowledge in the different sciences where biological hazards may be present (IV-B-2-a-(1)).

The IBC will also have the capability to assess the safety of rsNA research and instructional activities, and to identify any potential risk to public health or the environment.

The committee shall consist of at least 5 faculty members (Chair and Ph.D. or M.D. researchers), two community representatives, at least one laboratory/facility representative, the University Biosafety Officer, and *ex officio* members (IV-B-2-a-(1)).

1. Constituent Membership will include faculty and/or staff with at least the following expertise. As needed, the IBC will appoint members from various disciplines.
    - Animal environment, husbandry, containment principles, and management (IV-B-1-e);
    - Recombinant, synthetic nucleic acid and genetic engineering technology (IV-B-2, IV-B-2-a-(2));
    - Molecular biology;
    - Work with pathogens and BSL-2 containment;
    - Plant pathogen and plant pest containment principles (IV-B-1-d);
    - Laboratory techniques/management (IV-B-2-a-(2)).

2. *Ex officio* membership will include, at least, the following positions:
    - Assistant Vice President for Environmental Health and Safety (or designee)
        - Provides expertise in biological safety (IV-B-2-a-(2)).
    - Attending Veterinarian (or designee)
        - Provides expertise in concerns relating to animal care and use (IV-B-1-e).
    - University Biosafety Officer (IV-B-1-c, IV-B-2-a-(2))

III.B Conflict of Interest (IV-B-2-a-(4))

1. No member of the IBC may participate (except to provide information requested by the IBC) in the review or final approval of a project in which s/he has been, or expects to be, engaged, or has a direct financial interest.
2. If the IBC Chair's research is under review, the Vice Chair will lead the discussion of the protocol.

III.C Process for Appointment of IBC members

1. Faculty and staff shall be recommended by Department Heads/Chairs, Deans, Center Directors, or the IBC. Members are appointed, in writing, by the Vice President for Research and Innovation (IO).
2. The Chair shall be nominated by the IBC and appointed, in writing, by the Vice President for Research and Innovation (IO) (IV-B-2-a-(3)).
3. The Vice Chair shall be nominated by the IBC and appointed, in writing, by the Vice President for Research and Innovation (IO).

III.D Terms of Service

1. Chair
    - Terms are up to five years.
    - There is no limit to the number of terms a Chair may serve as long as they have met the membership expectations, they have been endorsed by their respective Department Head and re-appointed by the Institutional Official.
2. Vice-Chair
    - Terms are up to three years (in alignment with member terms).
    - There is no limit to the number of terms a Vice-Chair may serve as long as they have met the membership expectations, they have been endorsed by their respective Department Head and re-appointed by the Institutional Official.
3. Voting members
    - Terms are up to three years.
    - There is no limit to the number of terms a member may serve as long as they have met the membership expectations, they have been endorsed by their respective Department Head and re-appointed by the Institutional Official.
4. *Ex-Officio* voting member
    - indefinite appointments, following VT employment of the position, are made by the IO for the person holding the position.
5. Removal of Appointment - Early Term Termination
    - Individual Member requests to be removed from service
        - The member should submit a request to the IBC Program Director;
        - The Chair will approve the early termination.
    - IBC Chair directed member termination
        - The IBC Chair may elect to terminate a member's appointment at any time during a term for several reasons, including, but not limited to, the following:

(i.) not fulfilling IBC membership expectations, duties, and responsibilities;
(ii.) ongoing conflict of interest;
(iii.) at the discretion of the IBC Chair.

- The IBC Chair will notify the IO of the intent to terminate the member's appointment.
- The IO will officially notify the member, in writing, that the membership has been terminated.

6. Re-appointment of IBC members:
    - Three months prior to the expiration of member terms the IBC Program Director sends the list of re-appointments to the IBC Chair.
    - The IBC Chair reviews the members and determines those that will be offered a reappointment of up to three-year term.
    - The IBC Program Director will contact the member(s) for reappointment to verify if the member(s) are willing to serve another term.
        - If no, the member's Department head is contacted for a new nomination.
        - If yes, the VP for Research and Innovation will be notified, and will send a letter of re-appointment to the member.

III.E IBC Member Duties and Responsibilities, and Expectations

1. Chair – Leads IBC meetings, confirms meeting quorum, confirms required experts for protocol review are present, and reviews and approves exempt protocol and minor amendment submissions.
2. Vice Chair - performs the duties of the Chair when the Chair is unavailable or has a conflict of interest.
3. Attending Veterinarian - Provides expertise in concerns relating to animal care and use, and in containment of animals housed in non-standard housing.
4. Alternates
    - Only the University BSO has alternates appointed. The alternate will attend the IBC meeting as needed, and will act as the voting member in place of the *ex officio* member.
5. General Members (includes Chair, Vice Chair and Ex-Officio members)
    - Meeting Attendance Requirements
        - Virginia Tech employee members: as required for expertise. More than 3 absences when attendance is requested, without a substantial reason, will be discussed with the member by the Chair and removal from IBC will be discussed.
        - Community members: At least one member should be in attendance at each meeting but is not required if the members have reasonable excuses. More than 3 absences without a reasonable excuse, will be discussed with the member by the Chair and removal from IBC will be discussed.
    - Members Shall:
        - Communicate if they are unable to perform monthly IBC duties with

the IBC Program Director.

- Prepare for IBC meetings by reviewing the Agenda and IBC protocols.
- Provide guidance, or review, of protocols when requested by the IBC Program, EHS, and/or IBC Chair.
- Subcommittee participation - Volunteer or participate as requested by the Chair.
- When appointed by the Chair serve as Primary, or Secondary, Reviewer of protocols/amendments scheduled for review at IBC convened meetings.
- Petition the IO for identified resources needed to meet institutional compliance with appropriate regulations.

IV IBC Responsibilities

IV.A NIH *Guidelines* Required Responsibilities (IV-B-2)

1. Review research involving the use of rsNA for compliance with the *NIH Guidelines* and approve research projects that are in compliance with the *NIH Guidelines* (IV-B-2-b-(1)).
2. Notify the PI of the results of the IBC's review and approval (IV-B-2-b-(2)).
3. After completing a risk assessment, lower containment levels for certain experiments as specified in Section II-D-2-a of the *NIH Guidelines* (IV-B-2-b-(3)).
4. Set the containment levels for experiments specified in Sections III-D-4-b and III-D-5 of the *NIH Guidelines* (IV-B-2-b-(4)).
5. Periodically review research involving the use of rsNA and other biohazardous agents for compliance with the *NIH Guidelines* and BMBL. This occurs during the triennial renewal of non-exempt protocols (IV-B-2-b-(5)).
6. Adopt the emergency plans covering accidental spills and personnel contamination involving rsNA, as provided by Environmental Health and Safety IV-B-2-b-(6)).
7. Report any significant problems with or violations of the *NIH Guidelines*, as well as any significant research-related accidents or illnesses, to the IO (VP for Research and Innovation) and NIH OSP within 30 days unless the IBC determines a sufficient report has been submitted to both entities by the PI (IV-B-1-j, IV-B-2-b-(7)).
8. Will not authorize initiation of experiments which are not explicitly covered by the *NIH Guidelines* unless the NIH establishes the containment required (IV-B-2-b-(8)).
9. Determine if enrollment in a health surveillance program is necessary for staff, students and faculty involved in rsNA research. If the IBC determines that enrollment is needed, the personnel will be required to submit the online medical surveillance survey to occupational health for review by the occupational health nurse (IV-B-1-i).
10. Annually update our roster with the NIH OSP, or when a change is made to the roster. The IBC Program Director is registered as the non-voting contact for the IBC and will submit the update as needed (IV-B-2-a-(3)).

IV.B Virginia Tech Delegated Responsibilities (IV-B-1, IV-B-2-b-(9))

1. Establish and implement university policies and procedures that ensure the safe conduct of research and instructional activities, and work utilizing biohazardous materials (IV-B-1-a).
2. Review risk assessments and activities, involving biohazardous agents, not covered by other compliance committees and make recommendations for acceptance or rejection.
3. Establish procedures for correcting violations and advising university administration to terminate or curtail research/instructional work that is not in compliance.
4. Serve as technical and regulatory experts for scientific research and instructional activities involving biohazardous materials.
5. Advise and work with other health and safety committees as needed to ensure compliance.
6. Establish minimum personnel and training qualifications for work with biohazardous materials (IV-B-1-h, IV-B-7-d-(2)).
7. The IBC members receive training on the NIH Guidelines and VT IBC processes. New members are trained prior to their attendance at their first IBC meeting. Periodically, all members receive refresher training during one of the IBC meetings, typically every 2-3 years (IV-B-1-h).
8. Serve as a forum for the discussion of environmental, health, and safety issues that affect instructional and research activities involving biohazardous materials.
9. Provide input to the University Biosafety Officer and other EHS personnel on university health and safety program elements.
10. Review incidents involving biological agents that may have a university-wide impact and recommend course of action.
11. Work with university administration to obtain necessary resources to meet compliance.
12. Provide annual report to Vice President for Research and Innovation, and the Vice President for Operations on committee actions during the year. The report will contain, but will not be limited to, the following information:
    - Overall status of the IBC
      - Number of protocols reviewed by the full committee that year
      - Number of protocols disapproved that year and the reasons
      - List of non-compliance reports brought to the attention of the IBC and outcomes
    - Facility deficiencies brought to the attention of the IBC
    - Results of annual NIH self-assessment completed by the IBC Program Director
    - Additional information/concerns from the IBC members
    - List of any protocols sent to the IRE for DURC review
13. Review the charter, at least annually, and update as needed.

IV.C IBC Authority

The Institutional Biosafety Committee has the authority to:

1. Evaluate protocols and make recommendations for improvement to researchers, instructors and University Biosafety Officers (IV-B-1-g).
2. Review research and teaching activities and facilities for compliance with regulations and standards of practice, as needed (IV-B-2-b-(1)).
3. Obtain information and input regarding biohazard practices from university personnel upon request.
4. Terminate, suspend, or modify lab procedures or activities which violate federal, state, or local regulations or university policies regarding biohazardous materials.

V IBC Meetings

1. The IBC meets at convened meetings, which are open to the public. If necessary, the IBC Chair can close a portion of a meeting to the public (IV-B-2-a-(6), IV-B-2-a-(7)).
2. The IBC meets monthly and meeting dates are posted on the VT IBC website and are accessible to the general public (IV-B-2-a-(6), IV-B-2-a-(7));
3. Quorum has been set as the attendance of a minimum of 5 members with expertise in the fields of research being discussed (IV-B_2-a-(1));
4. All approved IBC meeting minutes are maintained by the IBC Program. The AVP for Scholarly Integrity and Research Compliance and a representative from Virginia Tech's Legal Counsel will respond to requests for copies of the approved meeting minutes. If necessary, the minutes will be redacted prior to responding to the request (IV-B-2-a-(7));
5. Comments received from the public regarding the IBC's actions will be referred to the IBC Chair, University BSO, and AVP for Scholarly Integrity and Research Compliance for review and to draft a response. The response will be sent to the IO for review and approval. The IBC Program Director will forward the original public comment(s) and Virginia Tech's response to the NIH OSP (IV-B-2-a-(7));
6. A meeting agenda, and other relevant meeting materials approved by the IBC Chair, are made available to all IBC members in advance of the meeting for IBC member review.

VI. Administrative and Professional Support to the IBC

VI.A Institutional Official

1. Appointment: Virginia Tech Research Policy 13030 appoints the "Institutional Official" as the Vice President for Research and Innovation and has formally delegated to the IO the authority to appoint the IBC Chair and its members.
2. Role and responsibilities:
    - serves as the responsible institutional official for applicable government entities;
    - provides administrative and financial support for programs and facilities involving the use of biohazardous agents;
    - appoints IBC members;
    - supports the successful execution of IBC responsibilities and authorities.

VI.B Scholarly Integrity and Research Compliance IBC Program staff:

1. The IBC Program is comprised of 1 full-time IBC Program Director and 1 full-time Senior IBC Program Protocol Coordinator.
2. Assures compliance with the *NIH Guidelines* and Virginia Tech Policies;
3. Provides professional expertise in matters concerning the use of rsNA and biohazardous agents;
4. Facilitates implementation of IBC-approved policies and guidelines;
5. Prepares IBC meeting agendas, attends IBC meetings, and records meeting minutes;
6. Assesses IBC policies and develops new policies or changes to current policies for review and approval by IBC members;
7. Manages IBC protocol and amendment review and approval process according to IBC policies;
8. Notifies investigators of the amendment and protocol review status;
9. Provides guidance and assistance to investigators and IBC reviewers during protocol and amendment review process;
10. In concert with the Associate VP for Scholarly Integrity and Research Compliance, ensures completion and submission of required annual reports;
11. Monitors national, state and local regulatory trends and communicate regulatory changes to the appropriate individuals as necessary;
12. Administers IBC-approved post-approval monitoring programs;
13. Provides access to protocols and IBC records during regulatory body audits;
14. In concert with, and at the direction of the IBC Chair, provides liaison between faculty, university administrators, the IBC, and regulatory and funding agencies related to activities involving biohazardous agents;
15. Communicates with other institutional committees (e.g. Institutional Animal Care and Use Committee, Institutional Review Board, Radiation Safety Committee, etc.) and safety departments (e.g. Environmental Health and Safety) to ensure required safety compliances are addressed;
16. Sponsors and coordinates seminars and training programs for campus faculty, staff, and students on topics of appropriate biohazard use and regulatory compliance.

VII. Biosafety Regulations/Standards of Practice

See Appendix A

VIII. Revisions

November 13, 2018 New governance document format generated
April 9, 2019 Rev 1: Division names and staff titles updated, Section III.A updated

IX. Approvals

IBC Approval Date	Institutional Official Approval Signature and Date
11/13/18 meeting	
4/9/2019 meeting	

Appendix A: Biosafety Regulations/Standards of Practice/University Requirements

BIOSAFETY REGULATIONS					
Federal Authority	**Agency**	**Reference**	**Scope**	**Applies to…**	**Requirements**
Department of Health and Human Services	Centers for Disease Control and Prevention (CDC)	42 CFR Part 73: Possession, Use and Transfer of Select Agents and Toxins; Interim Final Rule	Specific list of human pathogens with potential for use as bioterrorist weapons	Any research or work requiring use of select agents listed by the CDC	• Registration and approval • Security risk assessment • Written plans • Inspections • Annual review • Records management • Safety • Training
Department of Agriculture	Animal and Plant Health Inspection Service (APHIS)	7 CFR Part 331 and 9 CFR Part 121: Agricultural Bioterrorism Protection Act of 2002; Possession, Use and Transfer of Biological Agents and Toxins; Interim Final Rule	Specific list of animal and plant pathogens with potential for use as bioterrorist weapons	Any research or work requiring use of biological agents and toxins listed by APHIS	• Registration and approval • Security risk assessment • Written plans • Inspections • Annual review • Records management • Safety • Training

BIOSAFETY REGULATIONS					
Department of Health and Human Services	Centers for Disease Control and Prevention (CDC)	USPHS 42 CFR - Part 71 Foreign Quarantine. Part 71.54 Etiologic agents, hosts, and vectors.	• A person may not import into the United States, nor distribute after importation, any etiologic agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director. • Any import coming within the provisions of this section will not be released from custody prior to receipt by the District Director of U.S. Customs Service of a permit issued by the Director (Centers for Disease Control and Prevention).	Anyone wishing to import an etiologic agent, host, or vector as defined by the USPHS	• PHS Permit • Proper packaging, labeling, documentation • Training • Documentation • Coordination of shipment with receiving party

BIOSAFETY REGULATIONS					
Department of Agriculture	Animal and Plant Health Inspection Service (APHIS)	• 9 CFR 122: Importation of Etiologic Agents of Livestock, Poultry, and Other Animal Diseases and Other Materials Derived from Livestock, Poultry, or Other Animals. Organisms or Vectors • 7 CFR 330: Federal Plant Rest Regulations • 5 CFR Parts 730-799: Export of Etiologic Agents of Humans, Animals, Plants and Related Materials. • 7 CFR 340.4: Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Where There is Reason to Believe are Plant Pests	Importation/exporting of regulated materials	Anyone wishing to import/export or transfer animal or animal products, plant or plant products, certain genetically engineered organisms, and veterinary biologics	• APHIS Permit (VS, PPQ, CVB, BRS) • Department of Commerce (DoC) License • Proper packaging, labeling, documentation • Training • Documentation • Coordination of shipment with receiving party
Department of State	Directorate of Defense Trade Controls (DDTC)	International Traffic in Arms Regulations (22 CFR 120-130)	ITAR places strict controls on the export of "defense articles" and "defense services." Any defense article, service, or related technical data found to be on the USML requires an export license to be exported, i.e., given to a non-US-person.	Anyone wishing to export a regulated item	• Export license for regulated items • Training

BIOSAFETY REGULATIONS					
Department of Commerce	Bureau of Industry Security (BIS)	15 CFR 774, Supplement 1, also known as the Department of Commerce's Commodity Classification List: Export Administration Regulations (EAR)	The primary focus of the EAR is to control the export of "dual-use" technologies; i.e., items that are used, or have the potential to be used, for military as well as non-military purposes if such export could adversely affect the national interests of the United States.	Anyone wishing to export a regulated item	• Export license for regulated items • Training
Department of Treasury	Office of Foreign Assets Control		Enforcement of embargoes and trade sanctions through licensing requirements for financial transactions and services of value to sanctioned countries, entities, and individuals.	Anyone wishing to export a regulated item	• Export license for regulated items • Training
Commonwealth of Virginia	Department of Health	12 VAC 5-90: Regulations for Disease Reporting and Control	Reporting of specific diseases and dangerous microbes and pathogens to the Department of Health	• Any entity of the Commonwealth • Student Health Services • Child and adult care services • Anyone conducting research with select agents	Reportable Diseases • Reporting of suspected or confirmed cases of listed diseases • Rapid reporting of specific contagious diseases • HIV infections • Toxic substance-related illness • Outbreaks • Unusual or ill-defined diseases or emerging or reemerging pathogens
Department of Labor	Occupational Safety and Health Administration (OSHA)	29 CFR 1910.1030: Bloodborne Pathogens Standard	All occupational exposure to blood or other potentially infectious materials	Employees with potential for exposure to human blood and/or body fluids	• Exposure Control Plan • Engineering and work practice controls • Personal protective equipment • Labels/signs • Waste management • Training and information • Opportunity to receive Hepatitis B vaccination

BIOSAFETY REGULATIONS					
Department of Transportation	Research and Special Programs Administration: Office of Hazardous Materials Safety	49 CFR Parts 100-185: Hazardous Materials Regulations	Transportation of hazardous materials in commerce	Anyone shipping hazardous materials (e.g., infectious substances and/or diagnostic specimens)	• Proper packaging, labeling, documentation • Training • Documentation
Environmental Protection Agency via Virginia Department of Environmental Quality	Waste Management	9 VAC 20-120: Regulated Medical Waste Regulations	• Cultures and stocks of microorganisms and biologicals • Human blood and body fluids • Tissues and other anatomical wastes • Sharps • Animal carcasses, body parts, bedding, and related wastes if intentionally infected • Spill clean-up debris if contaminated with RMW	Generators of regulated medical waste	• Proper packaging and labeling • Disposal off-site by approved incineration facility • Spill containment and cleanup kit • Records management • Storage facility requirements • Registration as transporter

BIOSAFETY STANDARDS OF PRACTICE/UNIVERSITY REQUIREMENTS					
Oversight Authority	**Agency**	**Reference**	**Scope**	**Applies to...**	**Requirements**
Department of Health and Human Services	CDC and National Institutes of Health	*Biosafety in Microbiological and Biomedical Laboratories*	• Bacterial agents • Fungal agents • Parasitic agents • Prions • Rickettsial Agents • Viral agents (other than arboviruses) • Arboviruses and related zoonotic viruses • Toxins of biological origin • Human cells and	• Any research (and associated facilities) utilizing infectious agents and/or biological toxins with or without animal models • Clinical laboratories • Animal facilities	• Risk assessment • Standard practices • Special practices • Safety equipment • Facility design • Transportation and transfer • Training • Security plan • Emergency response plan • Medical surveillance
World Health Organization		*Laboratory Biosafety Manual*	Same as above	Same as above	• Risk assessment • Codes of practice • Safety equipment • Facility design and commissioning • Health and medical surveillance • Safety organization and training • Waste management
Committee on Occupational Safety and Health in Research Animal Facilities	National Research Council	*Occupational Health and Safety in the Care and Use of Research Animals*	Protection of the health and safety of employees who care for and use research animals	Individuals with exposure to animals	• Risk assessment • Occupational health program participation

Department of Health and Human Services	National Institutes of Health	*Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Guidelines)*	Human, animal, and plant recombinant and synthetic nucleic acid research	Any entity or individual receiving funding from NIH to work with rDNA molecules	• Risk assessment • Proposal review • Periodic review of ongoing projects • Physical containment • Training • Periodic inspections by University Biosafety Officer •

BIOSAFETY STANDARDS OF PRACTICE/UNIVERSITY REQUIREMENTS					
Oversight Authority	**Agency**	**Reference**	**Scope**	**Applies to...**	**Requirements**
European Committee for Standardization (CEN)	CEN Workshop 31 – Laboratory biosafety and biosecurity	*CWA 15793:2008 Laboratory Biorisk Management Standard*	Sets requirements necessary to control risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities	Any entity or individual wishing to apply a formal management system to the control of biohazards and associated risks; utilizes the systems approach as adopted by the International Organization for Standardization (ISO)	• Biorisk management policy • Biorisk management system • Continual improvement • Planning for hazard identification, risk assessment, and risk control • Control objectives and monitoring • Biorisk management committee • Biorisk management advisor (BSO) • Scientific management • Occupational health • Facility management • Security management • Animal handling • Training, awareness, and competence • Continuity and succession planning • Inventory control and information • Work practices, decontamination, and personnel protection • Infrastructure and operational management • Transportation of bio agents and toxins

BIOSAFETY STANDARDS OF PRACTICE/UNIVERSITY REQUIREMENTS					
Oversight Authority	**Agency**	**Reference**	**Scope**	**Applies to...**	**Requirements**
Department of Health and Human Services	Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories	*Guidelines for Biosafety Laboratory Competency: MMWR 2011; 60 (Suppl): 1-24*	Defines expected essential competencies for working safely with biologic and other hazardous laboratory materials.	Academic/research and clinical settings; applies to entry level, midlevel, and senior level lab personnel	• Guidelines define four skill domain areas with clearly listed expected competencies for entry level, midlevel, and senior level lab personnel • Each entity must tailor these guidelines to the specific needs of the entity; they may be used to assess current skill and establish goals, plan training and educational needs, establish safety portions of position descriptions and job qualifications, etc.
Virginia Tech	Environmental Health and Safety	*EHS website*	All research labs utilizing agents potentially infectious to humans	Researchers and associated personnel with potential for exposure to infectious substances and biological toxins	• Lab inspection for all BSL2 and BSL3 labs • Laboratory-specific standard operating procedures
Virginia Tech	Environmental Health and Safety	*Exposure Control Plan*	All occupational exposure to blood or other potentially infectious materials	Anyone who may come into contact with human blood or body fluids via job duties or research projects	• Departmental or work area exposure control plan • Personal protective equipment use • Engineering controls • Training (initial and annual refresher)
Virginia Tech	Environmental Health and Safety	*Occupational Health Assurance Program*	OSHA listed hazards requiring monitoring and other university identified hazards	Anyone with potential exposure to infectious substances and/or biological toxins and animal exposure	• Case-by-case review and determination of necessary medical services • Hazard-specific tests and/or vaccinations, if available • Medical history and review by physician

BIOSAFETY STANDARDS OF PRACTICE/UNIVERSITY REQUIREMENTS					
Oversight Authority	**Agency**	**Reference**	**Scope**	**Applies to...**	**Requirements**
Virginia Tech	Office for Export and Secure Research Compliance	*Export and Sanctions Compliance Policy*	• EAR and ITAR exports • EINEMR Exports and Imports • AFAEAR Assistance • FACR Transactions	Applies to all university activities which may result in an export or sanctioned transaction with a foreign national, entity, or country requiring an export license or other government approval prior to the activity taking place.	• Export assessments • Review of research programs for compliance with applicable regulations • Export licensing guidance • Institutional self-audits • Compliance violations investigations • Training
Virginia Tech	Office of the Vice President for Research and Innovation	*ASM Guidelines for Biosafety in Teaching Laboratories*	Best practices for the use of microorganisms in teaching labs	All instructional laboratories at Virginia Tech that use microorganisms.	• Case-by-case review and determination of necessary biosafety practices and PPE requirements for lab staff and students.