Institutional Biosafety Committee		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-RE-320.3	Status: Final	Version Date: 3/17/2026 Effective Date: 3/17/2026

1. PURPOSE

This Standard Operating Procedure defines the standards of Institutional Biosafety review for research or work to be conducted at a VCU/VCU Health facility, affiliate, or participating site.

2. REQUIREMENTS

VCU and VCU Health are committed to the safe and ethical use of all biologically derived hazardous materials utilized in research at VCU/VCU Health facilities.

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.

The VCU Institutional Biosafety Committee (IBC) is the responsible entity for oversight of all research utilizing recombinant DNA (rDNA), biohazardous agents, and/or biological toxins. VCU's IBC is applicable to all research regardless of funding source. In addition to rDNA research, the IBC reviews and approves Memoranda of Understanding and Agreement (MUAs) for research involving Select Agents, certain Human, Plant, and Animal Pathogens and Biological Toxins. The IBC also oversees clinical trials involving any administration of rDNA and/or pathogens to human subjects; or other research projects conducted at or on the behalf of VCU and VCUHS.

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.

3. DEFINITIONS

Biohazardous Agent- Biological substances that pose a threat to the health of living organisms. These may include medical waste, samples of a microorganism, virus, or toxin. These agents are grouped as follows dependent upon the severity of the threat:

- *Risk Group 1 (RG1)*- agents **not** associated with disease in healthy adult humans
- *Risk Group 2 (RG2)*- agents associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available
- *Risk Group 3 (RG3)*- agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available
- *Risk Group 4 (RG4)*- agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available

Biological Toxin- A substance produced by select bacteria, fungi, plants, or fish or animals that can cause damage to a living organism.

VCU Memoranda of Understanding and Agreement (MUA)

Document outlining the research specific information as it pertains to the utilization of rDNA, biohazardous agents and/or biological toxins. There are two types of MUAs based upon the following:

- *MUA for Request for Institutional Review/Approval for Research Involving Biohazardous Agents and/or Recombinant DNA:* required for biological agents RG2 or higher; human blood, blood components, fluids, unfixed organs, tissues, and cell lines.
- *MUA for Clinical Trials and Other Human-Use Protocols Involving Recombinant DNA and Biohazardous Agents:* research involving the deliberate transfer of rDNA, or DNA, or RNA derived from rDNA, into human research participants (human gene transfer) and/or application of biohazardous agents to human subjects.

Recombinant DNA (rDNA) and synthetic nucleic acids

- Molecules that a) are constructed by joining nucleic acid molecules and b) that can be replicate in a living cells)ex: recombinant nucleic acids);
- Nucleic acid molecules that are chemically or by other means synthesized or amplified including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (ex: synthetic nucleic acids) or
- Molecules that result from the replication of either instance described above

4. PROCESS

A. The applicable MUA and all associated documents must be completed and submitted to the VCU Safety and Risk Management, Biosafety which houses the IBC for review and

approval. The MUA form can be found on the Institutional Biosafety Committee Website.

B. IBC approval is required prior to study/protocol submission to the VCU Institutional Review Board (IRB).

C. A completed and approved MUA is required prior to any research activity conducted for clinical research studies involving rDNA, biohazardous agents, and/or biological toxins.

D. Refer to VCU Safety and Risk Management and/or the VCU Biosafety Officer for additional information.

5. REFERENCES

A. VCU:

- Institutional Biosafety Committee Website; Office of the Vice President for Research and Innovation (OVPRI)
- Safety and Risk Management:
  - Biological Safety Section
    - Biological Safety Section - Guidelines
      - Biohazardous Agent/rDNA Material Registration Information Page
      - Memorandum of Understanding Agreement HUMAN use
  - Training

B. National Resources:

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition

C. HRPP Policies and Guidance; HRPP Toolkit

- HRP-309-Ancillary Review Matrix

Review/Revision History CR-RE-320		
Version No.	**Effective Date**	**Description**

CR-RE-320.3	3/17/2026	● Updated REQUIREMENTS section to align with NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ● Added language clarifying institutional requirement to establish and register an Institutional Biosafety Committee (IBC) for NIH-funded research ● Expanded IBC authority to include additional research oversight as delegated by VCU leadership (VPRI and AVP for SRM) ● Added oversight of Dual Use Research of Concern (DURC) and Institutional Review Entity (IRE) responsibilities ● Expanded DEFINITIONS to include synthetic nucleic acids and updated recombinant DNA definition for alignment with current NIH terminology ● Clarified scope of research requiring MUA submission, including infectious agents and additional biohazardous materials ● Updated references to include HRPP Toolkit and ancillary review requirements ● Minor formatting edits and clarification of language throughout SOP
CR-RE-320.2a	07-01-2020	● Links updated
CR-RE-320.2	07-01-2020	● Biennial review performed ● Minor formatting edits ● Reference links added and updated
CR-RE-320.1	02-03-2018	● Original