VCU Environmental Health and Safety
Safety and Risk Management

Biohazardous Agent/rDNA Material Registration Information

Revised May 26, 2021

1. Purpose: The Biosafety Office works under the purview of the Institutional Biosafety Committee (IBC) and the Laboratory Safety Committee (LSC) to ensure that biohazardous agents and recombinant DNA (rDNA) materials are handled in compliance with National Institutes of Health/Centers for Disease Control (NIH/CDC) and other regulatory and credentialing agencies.

2. Scope / Applicability: In order to compile the needed documentation for verifying that all research is being conducted properly, the Biosafety Office requires researchers to complete the following registration forms when applicable:

   a. BioRaft Biological Registration

      1) All research involving the possession or manipulation (to include *in vitro* and/or *in vivo* applications) of biological agents classified at Biosafety Level-1 (BSL-1) or greater, CDC/USDA classified Select Agents, and/or recombinant DNA (rDNA) materials/synthetic nucleic acid molecules must be registered via the completion of the BioRaft Biological Registration (vcu.bioraft.com).

      2) Clinical trials and other human-use protocols involving recombinant DNA and biohazardous agents must register via completion of the "Memorandum of Understanding and Agreement (MUA) Form for Human Use"

   b. Institutional Animal Care and Use Committee (IACUC) Protocol Form (contact VCU Office of Research and Innovation/Animal Care and Use Program for access to IACUC forms)

      1) *In vivo* use of all biological agents classified at BSL-1/ABSL-1 or greater and any *in vivo* applications involving rDNA materials requires the completion of Drug/Compound list and appropriate Hazard Information Page(s) of the IACUC protocol Click Commerce form in addition to the BioRaft Biological Registration. Reportable Biological/rDNA hazards include, but are not limited to, fungi (living or dead), bacteria (living or dead), protozoans, helminthes, viruses/viral vectors (both replication competent and incompetent), prions, human or NHP (non- human primate) tumor cell lines, unfixed clinical specimens, human or NHP blood, tissue samples, or cell cultures, biotoxins* (e.g., tetrodotoxin, botulinum toxin, etc.), and adjuvants* and bioactive cellular constituents* Freund's complete adjuvant, LPS, etc.), and rDNA/synthetic nucleic acid molecules administered to live animals. If the protocol involves CDC/USDA select agents, additional

registration requirements must be completed prior to acquiring the material.

*Biotoxins, adjuvants, and bioactive cellular constituents are designated and reported as "chemical" hazards on the IACUC protocol.

c. Transgenic Organisms:

1) Transgenic mice which are created, bred, purchased, or transferred into the institution and can be housed at Animal Biosafety Level 1 (ABSL-1) need to be included on the Bioraft Biological Registration.

2) Transgenic rodents containing a transgene encoding more than 50% of an exogenous eukaryotic virus and transgenic rodents in which the transgene is under control of a gammaretroviral promotor (Gammaretrovirus is a genus of the retroviridae family which includes species of murine leukemia virus and feline leukemia virus) must be registered with the IBC via the BioRaft Biological Registration.

3) Rodents, which are transfected via viral vectors and/or require housing at Animal Biosafety Level 2 (ABSL-2) or above, must also be reported to the IBC via BioRaft Biological Registration Please contact the Biosafety Office (Mike Elliott: 400-4984), mtelliot@vcu.edu or Virginia Sykes: 828-2950, vwsykes@vcu.edu) for assistance or any additional information.

*Full details of the nature and origin of the transgenic strains will need to be included within the associated IACUC protocol.

3. Procedure / Process / Guidelines / Steps:

a. Hazard Assessment: Conduct a hazard assessment to determine the appropriate biosafety level and/or NIH classification (rDNA) of agents to be utilized in research protocols.

1) Common Pathogens: Appropriate BSLs for a number of pathogens which are commonly utilized in research are established in the NIH/CDC manual: *"Biosafety in Microbiological and Biomedical Laboratories, 6th Edition"* (BMBL). The BMBL should be the primary document referenced whenever conducting hazard assessments involving biological agents. The websites maintained by the American Biological Safety Association (ABSA) and the Health Canada Biosafety Office also provide credible resources which may be utilized for completion of hazard assessments.

2) Unknown or Emerging Pathogens: If the agents are not addressed in the above resources or other credible scientific literature, contact the Biosafety Office directly prior to attempting registration.

3) Recombinant DNA materials: Refer to the *"NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules"* (NIH Guidelines) to determine the section of the guidelines, which your rDNA research is classified.

- Section III-A through Section III-D "nonexempt" applications: IBC approval and registration prior to initiation. All studies will require completion of the BioRaft Biological Registration; *in vivo* applications will further require completion of the Drug/Compound list and appropriate Hazard Information Page(s) of the IACUC protocol.

- Section III-E "nonexempt" applications: please note that although the NIH Guidelines allow simultaneous notification of IBCs with the onset of commencing III-E applications, the university requires IBC notification, approval, and registration prior to initiating any section III-E applications. Notification will be provided via completion of the BioRaft Biological Registration and IACUC Drug/Compound list and appropriate Hazard Information Page(s) of the IACUC protocol (*in vivo* applications only).

- Section III-F "exempt" rDNA applications: although the NIH Guidelines indicate that IBC registration of III-F protocols is not required, the university requires full IBC review and registration of all protocols involving the possession or use of rDNA materials and nucleic acids including those involving III-F ("exempt") materials/applications.

- For assistance in determining NIH status, refer to the rDNA Information Page, NIH Guidelines, or contact the Biosafety Office.

b. Register Agents:

1) BioRaft Biological Registration: Log into BioRaft (vcu.bioraft.com) with a valid VCU eID and complete the Biological Registration Wizard. Supplemental documents, such as procedural SOPs and/or any other support documentation in Word format, can be copy/pasted into BioRaft under "Description of Experimental and Procedural Details" in the "Project Summary" section of the Registration.
Points to consider:

- Final approval of all BioRaft Biological Registrations will be contingent upon the laboratory's satisfactory participation in the university Laboratory Safety Program and/or a facility inspection.

- Biological Registrations involving any NIH rDNA applications will require approval from the full Institutional Biosafety Committee (IBC). In order to be included on the monthly IBC review docket, the Biological Registration is required to be submitted for review by the Biosafety Office by the first Thursday of each month and to be revised to acceptable form for final review by the second Thursday of the month.

2) IACUC Protocols: require the completion of the Drug/Compound list and appropriate Hazard

Information Page(s) of the IACUC protocol submission form. Access is provided through accessing the standard IACUC protocol form provided through the Office of Research and Innovation/RAMS Systems link: https://research.vcu.edu/resources/animal-research/ . The Biosafety Office will not grant approval until all details of the Drug/Compound list and appropriate Hazard Information Page(s) are completed and included in the up-to-date electronic version displayed on the VCU RAMS System. https://research.vcu.edu/rams-systems/. The Biosafety Office encourages PIs to communicate with our office during the protocol development stage to ensure that the Drug/Compound list and appropriate Hazard Information Page(s) are complete/acceptable prior to posting on prior to submitting the protocol for IACUC review. Following approval of the BioRaft Biological Registration and review of IACUC, the Biosafety Office will issue an IBC hazardous materials approval which should be uploaded into the VCU RAMS System. PIs should also be aware of the following points:

- IACUC protocols involving biohazardous agents classified at BSL-1 or greater and/or NIH rDNA applications will not be approved by the Biosafety Office prior to the IBC approval of the BioRaft Biological Registration.

- IACUC protocols involving any NIH rDNA applications will require full committee approval from the IBC. The IBC meets monthly to conduct reviews of protocols under its purview. Contact the Biosafety Office for information regarding upcoming meeting locations, times, and dates.

Questions or comments regarding this information page should be directed to the Biosafety Office.