VCU Biosafety Office

Biohazard Registration Information Page

(revised 05/28/09)

I. PURPOSE: The Biosafety Office works under the purview of the Institutional Biosafety Committee (IBC) and the Chemical/Biological Safety Committee (CBSC) 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. In order to compile the needed documentation for verifying that research is being conducted properly, the Biosafety Office requires researchers to complete the following registration forms when appropriate:

A. Memorandum of Understanding and Agreement (MUA): All research involving *in vivo* and *in vitro* use or manipulation of biohazardous agents classified at Biosafety Level-2 (BSL-2) or greater and/or NIH nonexempt classified rDNA must be registered through the completion of an MUA. Refer to the rDNA Registration Information Page for additional information regarding rDNA classification and registration.

B. IACUC Appendix C: *in vivo* use of agents BSL-2/ABSL-2 or greater requires the completion of Appendix C of the IACUC protocol in addition to an MUA.

C. Transgenic Organisms: Acquisition, creation, other research involving transgenic plants and animals requires submission of:

1. Transgenic Animals: Transgenic Animal Registration Form

2. Transgenic Plants: Transgenic Plant Registration Form

II. PROCEDURES

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 (BMBL). The BMBL should be the primary document used whenever conducting hazard assessments involving biological agents. The websites maintained by the American Biological Safety Association 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. rDNA materials: Refer to the NIH Guidelines to determine which section of the guidelines which your rDNA research is classified:

a. Section III-A through Section III-D.* applications require IBC approval and registration prior to initiation. All studies will require completion of an MUA, *in vivo* applications will further require completion of Appendix C of the IACUC protocol.

b. Section III-E applications require IBC notification prior to initiating, notification will be provided via completion of an MUA and IACUC Appendix C (*in vivo* applications only).

c. Section III. F "exempt" rDNA applications do not require completion of MUA or IACUC Appendix C

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

* Experiments falling under Section III-A through Section III-C will require direct approval from NIH in additional to institutional (IBC) approval prior to initiating.

B. Register Agents:

1. MUA: Submit completed documents via campus mail (OEHS, PO Box 980112 Attn: Biosafety Office) or electronically to the Biosafety Office. Points to consider:

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

b. MUAs involving NIH nonexempt rDNA applications will require approval from the full Institutional Biosafety Committee (IBC). In order to be placed on the monthly IBC review docket, MUAs are required to be submitted to 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 Appendix C**:** Access to Appendix C is provided through accessing the standard IACUC protocol form provided at the VCU Research Office (VCUeRA) website. The Biosafety Office will not grant approval until all details of Appendix C are completed and included in the up-to-date electronic version displayed on the VCUeRA system. The Biosafety Office encourages PIs to communicate with our office during the protocol development stage to ensure that Appendix C is complete/acceptable prior to posting on VCUeRA. Following receipt of the MUA and review of Appendix C, the Biosafety Office will issue an IACUC hazardous materials approval sheet which should be uploaded into the VCUeRA system. PIs should also be aware of the following points:

a. IACUC Appendix C forms involving biohazardous agents classified at BSL-2 or greater and/or NIH nonexempt rDNA applications ***will not*** be approved by the Biosafety Office prior to the issuance of an approved MUA.

b. IACUC Appendix C forms involving NIH nonexempt rDNA applications will require full committee approval from the IBC. The schedule for document submission/revision is the same as indicated above in section II.B.1.b.

3. Transgenic Organisms: Transgenic organisms include knock out, knock in, and any other heritable mutation. Submit completed documents via campus mail (OEHS, PO Box 980112 Attn: Biosafety Office) or electronically to the Biosafety Office. The Biosafety Office will not grant approval to any IACUC protocol involving use of transgenic organisms which has not been registered with our office via submission of a Transgenic Animal Registration Form or Transgenic Plant Registration Form.

Questions or comments regarding this information page should be directed to the Biosafety Office at extension 400-4984.