Office of Environmental Health and Safety

RECOMBINANT DNA AND BIOHAZARD INFORMATION PAGE

(Revised March 22, 2006)

I. Biohazard/Recombinant DNA Definition:

A. A biohazardous (etiological) agent is an infectious (pathogenic) substance produced from living organisms that has the potential for causing disease in other living organisms.

B. The National Institutes of Health (NIH) define recombinant DNA (rDNA) molecules as "molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from the replication of those described above." Synthetic DNA segments that are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, it is exempt from the NIH Guidelines.

C. All rDNA research as explained below must be conducted in compliance with the "NIH Guidelines for Recombinant DNA Research"

II. Applicability of NIH rDNA Guidelines

A. The guidelines affect rDNA research that is conducted or sponsored by an institution that receives funding from NIH, including research performed directly by NIH. An individual who receives support for research involving recombinant DNA must be associated with or sponsored by an institution that assumes the responsibilities assigned in the NIH guidelines.

B. The guidelines also include research or participation in research that involves human testing of materials containing recombinant DNA developed with NIH funds ("participation" to include research collaboration and/or contractual agreements, and not mere provision of research materials).

III. Requirements of NIH rDNA Guidelines

A. Institutional Biosafety Committee (IBC):

1. General Requirements: In accordance with the NIH Guidelines, an IBC must be established by all institutions conducting research involving rDNA or biohazardous agents (including all human blood/tissues laboratories). The IBC must be comprised of:

a. No fewer than five members so selected that they collectively have experience and expertise in rDNA technology and the capability to assess the safety of

recombinant DNA/Biohazardous research and to identify any potential risk to public health or the environment.

b. At least two of the members shall represent the community.

c. At least one individual shall have expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, Physical and Biological Containment for Recombinant DNA Research Involving Plants, require prior approval by the IBC.

d. At least one scientist shall have expertise in animal containment principles when experiments utilizing Appendix Q, Physical and Biological Containment for Recombinant DNA Research Involving Animals, require IBC prior approval.

e. A facility Biological Safety Officer (BSO) is mandatory when performing research at Biosafety Level-3 or above.

2. Mission of the Virginia Commonwealth University (VCU) IBC:

a. To establish, review, and revise guidelines under which research involving rDNA, biohazardous agents, carcinogens, and acutely toxic compounds is conducted at VCU.

b. To review all proposed research protocols involving rDNA, biohazardous agents, carcinogens, acute toxins and any other proposed procedures involving significant biohazardous risks.

c. To periodically review all ongoing rDNA, high-risk chemical carcinogens, and biohazard research to ensure appropriate biosafety guidelines are followed.

d. To advise the university of procedures and infrastructure that may be necessary to conform to established guidelines.

e. To maintain close and continuous association with the Office of Environmental Health and Safety, utilizing it as the main resource for providing consultation, laboratory inspections, monitoring, record keeping, and training.

f. To identify chemical substances used in VCU laboratories that may pose a carcinogenic and/or acute toxin exposure threat.

g. To establish and review policies and procedures used for the control, processing, and disposal of regulated medical waste and hazardous chemical waste.

h. To establish procedures for correcting violations in order to comply with applicable laws, regulations, and guidelines.

i. To inform VCU administrators whenever compliance deficiencies are revealed.

j. As required, the IBC will consult with appropriate individuals outside the committee.

B. Registration of Research

1. All university research involving rDNA and biohazardous agents must be registered with the IBC.

a. Registration with the IBC is accomplished through completing and submitting a Memorandum of Understanding and Agreement (MUA) form (available for download in Microsoft Word).

b. Initial and ongoing approval of the research project will be contingent upon the IBC review of the MUA and annual laboratory certification through the biosafety inspection program (refer to Section III.C. for more information regarding the biosafety inspection program).

2. Principal Investigators (PIs) will be responsible for registering with the IBC and for following all applicable guidelines regarding recombinant DNA and biohazardous research.

3. Failure to register rDNA and/or biohazardous research with the IBC or non-compliance with other regulatory guidelines may result in:

a. Suspension, limitation, or termination of financial assistance for the noncompliant NIH-funded research project and of NIH funds for other recombinant DNA research at the institution.

b. Requirement for prior NIH approval of any or all recombinant DNA projects at the institution.

c. Sanctions under the IBC Violations Policy.

4. Principal investigators shall be responsible for conducting risk assessments and determining Biosafety Levels (BSLs) for all research conducted within laboratory spaces under their charge. Refer to Section IV for more information regarding risk assessment, BSLs, and the principles of biosafety.

5. For information regarding IBC registration process please contact the Biosafety Inspector (Larry Mendoza) at 827-0353.

C. Annual Biosafety Inspection:

1. Laboratories registered with the IBC for research involving rDNA and/or biohazardous agents will be subjected to annual biosafety inspections that meet the following criteria:

a. All biohazard laboratory inspections will be performed per the requirements of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories manual. For a copy of the biosafety lab inspection checklist please contact Larry Mendoza at 827-0353.

b. All laboratory inspections will be conducted on a yearly basis and will be scheduled in advance whenever possible, unannounced random and follow-up inspections may also be conducted from time to time, however.

2. Immediate life/property threatening violations and continuing violations revealed during the inspection process will be reported to the IBC.

3. Following the completion of the biosafety inspection, a summary and recommendations will be provided to the laboratory.

4. For more information regarding the biosafety inspection program please contact Larry Mendoza at 827-0353.

IV. Principles of Biosafety

A. The CDC/NIH identify three basic principles of Biosafety:

1. Risk Assessment: It is the responsibility of the PI to assess the risk which the research poses to the health and safety of laboratory staff and the environment. Based on this risk assessment, the PI must ensure that the proper precautions as indicated in the CDC/NIH text: Biosafety in Microbiological and Biomedical Laboratories (BMBL) are followed.

2. Containment: Containment is used to describe safe methods for managing infectious materials in the laboratory environment. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents.

3. Biosafety Levels: Biosafety Levels (BSLs) use various elements of containment to ensure a safe laboratory environment when working with biohazardous or infectious agents. There are 4 biosafety levels.

a. Biosafety level 1: Least amount of protection and is used with well-characterized agents not known to consistently cause disease in healthy adult humans. Example: E. coli (non-pathogenic strain), infectious canine hepatitis virus.

b. Biosafety level 2: Suitable for work involving agents of moderate potential hazard to personnel and the environment. Example: human tissue and blood, hepatitis B, HIV, adenoviruses.

c. Biosafety level 3: Suitable for work with infectious agents that may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Example: M. tuberculosis, St. Louis encephalitis virus.

d. Biosafety level 4: Required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. Example: Ebola virus, arenavirus, Marburg virus. VCU is not eligible to perform research at the Biosafety level 4.

4. For additional information regarding BSL determination and the principles of biosafety please visit the BMBL.