

VCU Office of Environmental Health and Safety

Recombinant DNA Information Page

(revised 05/29/09)

I. INTRODUCTION: At Virginia Commonwealth University, all research involving the use or manipulation of recombinant DNA (rDNA) is subject to the oversight of the [Institutional Biosafety Committee](#) (IBC). The IBC's mission is to ensure that all research involving rDNA is conducted in accordance with the National Institutes of Health Recombinant DNA Guidelines ([NIH Guidelines](#)) and other governmental regulatory and credentialing agencies. The [NIH Guidelines](#) specify practices for constructing/handling recombinant deoxyribonucleic acid (DNA) molecules and organisms and viruses containing recombinant DNA molecules, and classify rDNA experiments into two broad classes: "exempt" (not covered by NIH Guidelines) and "nonexempt" (covered under NIH Guidelines) applications.

II. ATTAINING IBC COMPLIANCE:

A. Determine the section of the [NIH Guidelines](#) which your rDNA applications are classified: The six categories of rDNA research described in [Section III](#) of the NIH Guidelines are summarized below, researchers are advised to refer directly to the NIH Guidelines when determining appropriate classification(s) for their research:

1. Section III-A "Experiments that require IBC approval, *RAC review, and NIH Director approval before initiation, major actions under the *NIH Guidelines*": Includes the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

*RAC: NIH Recombinant DNA Advisory Committee

2. Section III-B "Experiments that require NIH/*OBA and IBC approval before initiation, experiments involving the cloning of toxin molecules with LD₅₀ of less than 100 nanograms per kilogram body weight": Includes deliberate formation of recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD₅₀ of less than 100 nanograms per kilogram body weight.

*OBA: Office of Biotechnology Activities

3. Section III-C "Experiments that require IBC and Institutional Review Board approvals and RAC review before research participant enrollment, experiments involving the deliberate transfer of rDNA, or DNA

or RNA derived from recombinant DNA, into one or more human research participants”: No research participant shall be enrolled until the RAC review process has been completed.

4. Section III-D. “Experiments that require IBC approval before initiation”

a. “Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or restricted agents as host-vector systems” (III-D-1)

b. “Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or restricted agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems” (III-D-2)

c. “Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems” (III-D-3)

d. “Experiments involving whole animals”: experiments involving generation of transgenic rodents that require BL1 containment are described under [Section III-E-3, *Experiments Involving Transgenic Rodents*](#). The purchase or transfer of transgenic rodents is exempt from the *NIH Guidelines* (III-D-4)

e. “Experiments involving whole plants” (III-D-5)

f. “Experiments involving more than 10 L of culture” (III-D-6)

5. Section III-E “Experiments that require IBC notice simultaneous with initiation”: Experiments not included in Sections [III-A](#), [III-B](#), [III-C](#), [III-D](#), [III-F](#):

a. “Experiments involving the formation of rDNA molecules containing no more than 2/3 genome of any eukaryotic virus” (III-E-1)

b. “Experiments Involving Whole Plants not falling under Section [III-A](#), [III-B](#), [III-D](#), or [III-F](#).” (III-E-2)

c. “Experiments involving transgenic rodents”: Generation of rodents in which animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into germ-line (transgenic rodents). Only experiments that require BL1 containment are covered under this section; experiments that require BL2, BL3, or BL4 containment are covered under [Section III-D-4](#). (III-E-3)

6. Section III-F. “Exempt Experiments”: The following rDNA molecules are exempt from the *NIH Guidelines* and registration with the IBC is

not required:

- a. “Those that are not in organisms or viruses” (III-F-1)
- b. “Those that consist entirely of DNA segments from single nonchromosomal or viral DNA source, though one or more of segments may be a synthetic equivalent (III-F-2)
- c. “Those consisting entirely of DNA from prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of same species), or when transferred to another host by well established physiological means” (III-F-3).
- d. “Those that consist entirely of DNA from an eukaryotic host including chloroplasts, mitochondria, or plasmids (excluding viruses) when propagated only in that host (or closely related strain of same species)” (III-F-4)
- e. “Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent” (III-F-5)
- f. “Those that do not present a significant risk to health or the environment as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment” (III-F-6)

B. IBC Required Registration Documents:

1. Section III-A through Section III-D* rDNA applications require IBC *approval and registration* (via full committee vote) prior to initiation. All studies will require completion of a Memorandum of Understanding and Agreement ([MUA](#)), *in vivo* applications will further require completion of Appendix C of the IACUC protocol.
2. Section III-E rDNA applications require IBC notification prior to initiating, notification will be provided via completion of an [MUA](#), an IACUC Appendix C will also be required if *in vivo* applications are involved.
3. Section III-F “exempt” rDNA applications do not require completion of MUA or IACUC Appendix C.
4. Experiments involving DNA-modified plants and transgenic animals (altered by stable introduction of recombinant DNA, or DNA derived there from, into the germ-line) as detailed under section III-E, and all purchase other acquisition of transgenic plants and animals must be registered via submission of:
 1. DNA-modified plants: [Transgenic Plant Registration Form](#)

2. Transgenic Animals: [Transgenic Animal Registration Form](#)

Submissions may be made via campus mail (OEHS, PO Box 980112, attn: Biosafety Office) or via email to the [Biosafety Office](#). If you have any questions regarding rDNA or other biosafety concerns please contact the Biosafety Office at 400-4984.