

APPENDIX: INSTITUTIONAL BIOSAFETY COUNCIL PROCEDURES

1. REGISTRATION OF RECOMBINANT DNA USE

1.1 Activities that are Exempt from the *NIH Guidelines*

According to the *NIH Guide*, the following molecules are exempt from the *NIH Guidelines*:

- a) Those molecules that are not in organisms or viruses.
- b) Those molecules that consist entirely of DNA segments from a single non-chromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
- c) Those molecules that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.
- d) Those molecules that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
- 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. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the NIH Recombinant DNA Committee (RAC) after appropriate notice and opportunity for public comment. See Appendices A-1 through A-VI, of the NIH Guidelines for Research Involving Recombinant DNA Molecules, 1/96 (NIH Guidelines).
- 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. See 1/96 (NIH Guidelines) Appendix C, Exemptions under Section III-E-6, for other classes of experiments, which are exempt from the NIH Guidelines.
- g) All such research must be conducted using Biosafety Level 1 (BL1) containment.

Activities with recombinant DNA that are exempt from the NIH Guidelines require registration with the IBC. The Chair of the IBC will review the registration to determine that the activities are exempt from the *NIH Guidelines*. The IBC reserves the authority to require proposal modifications regarding safety before determining the activities are exempt. No activities with recombinant DNA can be initiated until the IBC determines that the activities are exempt. If activities are determined to be exempt from the NIH Guidelines, there will be no continuing review (e.g., annual review) of the activities. Staff in the Office of Research Protections will notify the Principal Investigator (and faculty advisor if the PI is a student) of the results of the IBC's review.

1.2 Activities that require Notification in the *NIH Guidelines*

Activities with recombinant DNA that require IBC Notification in the *NIH Guidelines* (see Section III-E) require registration with the IBC. Activities with recombinant DNA can be initiated simultaneously with IBC notification as provided in Section III-E. Staff in the Office of

Research Protections will notify the Principal Investigator (and faculty advisor if the PI is a student) of the receipt of Notification of recombinant DNA activities.

1.3 Activities that require IBC Approval Before Initiation

Activities with recombinant DNA that require IBC approval before initiation as described in Section III-D of the *NIH Guidelines* will be reviewed by the IBC at a convened meeting.

The principal investigator must provide the following information in the Request for Review of Recombinant DNA Experiments to the IBC:

- Name(s) and department(s) of investigator(s)
- Title of the experiment
- Location of the experiment
- Use of Animal or Human Subjects
- Highest perceived Risk Group (RG)
- Containment Conditions (BL)
- Description of appropriate microbiological practices and laboratory techniques to be used
- Whether the experiments involve more than 10 liters of culture at one time
- Recipient organisms or cells to be used
- List the Host(s) and Vector(s) to be Used
- Nature of the inserted sequences (payload) and original source of the DNA
- Whether or not external funding is proposed
- Qualifications of investigator(s), e.g. a CV or experience in the specific research area
- Disclosure of any conflicts of interest
- Electronic Signature of Principal Investigator and responsible faculty member, if PI is a student

The Principle Investigator must adhere to the NIH Guidelines in the conduct of Recombinant DNA research and shall remain in communication with the Institutional Biosafety Council throughout the conduct of activities with recombinant DNA.

2. TRAINING

All personnel engaged in non-exempt activities with recombinant DNA must complete the [Collaborative Institutional Training Initiative](#) Biosafety training program which covers the necessary practices and techniques to ensure safety and the procedures for dealing with accidents.