

I. GUIDELINES FOR STUDIES INVOLVING RECOMBINANT DNA MOLECULES

A. POLICIES AND PROCEDURES:

The Guidelines for Research Involving Recombinant DNA Molecules issued by the Department of Health and Human Services (DHHS), National Institutes of Health (NIH) May 7, 1986 have been adopted as the standard for such studies at the Medical University of South Carolina (MUSC). The MUSC Policies and Procedures and the NIH Guidelines apply to all studies involving recombinant DNA molecules which are conducted by or under the direction of a MUSC investigator using University facilities, or involving University funds (including extramural funds administered by the University) and regardless of location of the work site. Approval and/or notification of the IBC is required prior to initiation of all research programs involving recombinant DNA molecules, except those experiments exempted by the NIH.

In the context of these Guidelines, recombinant DNA molecules are defined as either:

- (i) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell
- or-
- (ii) DNA molecules that result from the replication of those described in (i) above.

B. APPLICATION FOR APPROVAL OR REGISTRATION:

All research programs at MUSC involving recombinant DNA molecules, except those categories of research specifically exempted by the NIH Guidelines, require either approval by or registration with the Institutional Biosafety Committee (IBC). Approval or registration is required regardless of whether the research program is funded by an agency requiring such certification or not. All new, continuation, or renewal applications involving non-exempt recombinant DNA molecules submitted to the Office of Research and Sponsored Programs should be accompanied by the approval from the IBC. Approval from or notification of the IBC is also required whenever investigators initiate or significantly change research involving recombinant DNA molecules under existing grants or contracts.

To comply with institutional policies for studies involving recombinant DNA molecules, the Principal Investigator must submit to the Biosafety Committee a Recombinant DNA Registration Document (Appendix I) addressing the following points:

- source(s) of DNA;
- nature of inserted DNA sequences (including identification by name of the biological source);
- host(s) and vector(s) to be used;
- statement whether a deliberate attempt will be made to obtain expression of a foreign gene, and, if so, what protein will be produced;
- containment conditions as specified by the current NIH Guidelines;
- if applicable, information on medical surveillance; and,
- a signed statement that the Principal Investigator is familiar with the current NIH Guidelines and agrees to abide by their provisions, including a statement that the recombinant DNA molecules being used will not be transferred to other investigators or institutions unless their facilities and techniques have been assured to be adequate.

The Principal Investigator has the continuing responsibility to consider whether there is any reason that an increase in biocontainment practices or facilities may be appropriate in any ongoing program approved by the IBC. Should he/she perceive the need for any such increase, the investigator has the responsibility to notify the IBC and to institute the appropriate increases in the level of biocontainment. In contrast, the biocontainment practices and facilities approved by the IBC may not be decreased without prior approval by the IBC and by the funding agency and/or NIH/Office of Recombinant DNA Activities(ORDA) provided that such approval is required.

C. ROLES AND RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

The following section is adapted from the approved NIH Guidelines for Research Involving Recombinant DNA Molecules. The principles stated here apply to all studies at MUSC regardless of the source or type of funding. On behalf of MUSC, the Principal Investigator is responsible for complying fully with the MUSC Policy in conducting any recombinant DNA research.

1. General

The Principal Investigator shall:

- a. Ensure that IBC approval is obtained before initiating or modifying any research procedures which are classified as Class A or B according to the NIH guidelines (see Appendix I for classification descriptions);
- b. Notify the IBC of the use of research procedures which are classified as Class C experiments according to the NIH guidelines (see Appendix I for classification description);
- c. Report within 30 days to the IBC and to NIH (ORDA) all significant problems with and violations of the Guidelines and all significant research-related accidents and illnesses;
- d. Report to the IBC and to NIH (ORDA) new information bearing on the Guidelines;
- e. Be adequately trained in appropriate microbiological techniques;
- f. Adhere to IBC-approved emergency plans for dealing with accidental spills and personnel contamination; and,
- g. Comply with shipping requirements for recombinant DNA molecules. (See Appendix H of the Federal Register, May 7, 1986 for packaging and shipping requirements and the Laboratory Safety Monograph for Technical recommendations. The requesting laboratory must be in compliance with the NIH Guidelines and under appropriate review by its Institutional Biosafety Committee and the sending investigator must maintain a record of all shipments of recombinant DNA materials not exempt from the Guidelines.)

2. Submissions to NIH.

The Principal Investigator shall:

- a. Submit information to NIH (ORDA) with a copy to the IBC in order to have new host-vector systems certified;
- b. Petition NIH, with approval from the IBC, for exemptions to the NIH Guidelines (for additional information on procedures contact the IBC); and
- c. Petition NIH, with concurrence of the IBC for approval to conduct experiments specified in Section III-A of the May 7, 1986 Guidelines.

3. Submissions to the IBC

The Principal Investigator shall:

- a. Make the initial determination of the required levels of physical and biological containment in accordance with the NIH Guidelines;
- b. Select appropriate microbiological practices and laboratory techniques to be used in the research;
- c. Submit the initial research protocol (if the research procedures are classified as Class A, B, or C) and subsequent changes (e.g., changes in the source of DNA or host-vector system, which require a new or revised Registration Document) to the IBC for review and approval or disapproval;
- d. Remain in communication with the IBC throughout the conduct of the project; and,
- e. Provide to the IBC, upon request, a complete copy of the grant application or other pertinent material on which the Registration Document is based.

4. Prior to Initiating the Research the Principal Investigator is responsible for:

- a. Making available to the laboratory staff copies of the approved protocols that describe the potential biohazards and the precautions to be taken;
- b. Instructing and training staff in the practices and techniques required to ensure safety and in the procedures for dealing with accidents; and,
- c. Informing the staff of the reasons and provisions for any precautionary medical practices advised or requested, such as vaccinations or serum collection.

5. During the Conduct of Approved Research the Principal Investigator is responsible for:

- a. Supervising the safety performance of the staff to ensure that the required safety practices and techniques are employed;
- b. Investigating and reporting in writing to the Office of Recombinant DNA Activities, the MUSC Biological Safety Officer, and the IBC any significant problems pertaining to the operation and implementation of containment practices and procedures;
- c. Correcting work errors and conditions that may result in the release of recombinant DNA materials, or other related hazardous materials, into the environment;
- d. Ensuring the integrity of the physical containment (e.g., purity, and genotypic and phenotypic characteristics); and,
- e. Publications
Principal Investigators are urged to include, in all publications

reporting on recombinant DNA research, a description of the physical and biological containment procedures employed.