

Responsibilities of the Principal Investigator in Recombinant DNA Research*

A. Conduct in the Laboratory

The Principal Investigator shall:

- Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;
- Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biological Safety Officer, Greenhouse/Animal Facility Director, Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities;
- Correct work errors and conditions that may result in the release of recombinant DNA materials;
- Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics); and
- Comply with reporting requirements for human gene transfer experiments conducted in compliance with the NIH Guidelines.

B. Training Requirements (Prior to the Initiation of Research)

The Principal Investigator shall:

- Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;
- Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents; and
- Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

C. Additional Submissions to the Institutional Biosafety Committee

The Principal Investigator shall:

- Make an initial determination of the required levels of physical and biological containment in accordance with the NIH Guidelines;
- Select appropriate microbiological practices and laboratory techniques to be used for the research;
- Submit the initial research protocol and any subsequent changes (e.g., changes in the source of DNA or host-vector system) to the Institutional Biosafety Committee for review and approval or disapproval; and
- Remain in communication with the Institutional Biosafety Committee throughout the conduct of the project.

D. Other Responsibilities

The Principal Investigator shall:

- Initiate or modify no recombinant DNA research which requires Institutional Biosafety Committee approval prior to initiation until that research or the proposed modification thereof has been approved by the Institutional Biosafety Committee and has met all other requirements of the NIH Guidelines;
- Determine whether experiments are covered by Section III-E, *Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation*, and ensure that the appropriate procedures are followed;
- Report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to the Biological Safety Officer, Greenhouse/Animal Facility Director, Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities within 30 days. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax);
- Report any new information bearing on the NIH Guidelines to the Institutional Biosafety Committee and to NIH/OBA (reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax));
- Be adequately trained in good microbiological techniques;
- Adhere to Institutional Biosafety Committee approved emergency plans for handling accidental spills and personnel contamination; and
- Comply with shipping requirements for recombinant DNA molecules.

* These and additional requirements can be found in "NIH Guidelines for Research Involving Recombinant DNA Molecules."