

**POLICY– Responsibilities of PI
Conducting Research Using
Recombinant DNA or Infectious Agents**

Version 2.0

**Office for the Protection of Research Subjects (OPRS)
Institutional Biosafety Committee (IBC)**

1737 West Polk Street (MC 672)
206 Administrative Office Building
Chicago, IL 60612

Phone: 312.996.1972 Fax: 312.996.9088
www.research.uic.edu

I. Institutional Policy

These responsibilities are in part taken from the *NIH Guidelines for Research involving Recombinant DNA Molecules* (Section IV-B-7-d and Section IV-B-7-e).

A. Prior to Initiating Research

1. Submit an IBC protocol to the IBC office prior to initiation of any research involving rDNA or infectious agents (BSL2 and above).
2. Do not initiate research prior to IBC approval if any boxes are checked in review category I or II of IBC Form A- Protocol for Use of Recombinant DNA in Research or if submitting IBC Form B- Protocol for the Use of Infectious Agents.
3. Contact the IBC office if submitting a human gene transfer protocol prior to submission.
4. Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken.
5. Instruct and train laboratory staff in the following:
 - i. The practices and techniques required to ensure safety
 - ii. The procedures for dealing with accidents
6. Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g. vaccinations or serum collection).

B. During the Conduct of the Research

1. Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
2. Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the appropriate office:
 - i. The Biological Safety Officer
 - ii. Greenhouse Facility Director
 - iii. Animal Facility Director
 - iv. Institutional Biosafety Committee Office
 - v. NIH/Office of Biotechnology Activity
3. Correct work errors and conditions that may result in the release of recombinant DNA materials or infectious agents.
4. Ensure the integrity of the physical containment (e.g. biological safety cabinets) and the biological containment (e.g. purity and genotypic and phenotypic characteristics).
5. Comply with the reporting requirements for human gene transfer experiments conducted in compliance with the *NIH Guidelines- Appendix M*.
 - i. Submission of annual reports to OBA by PI or delegated sponsor and copied to the IBC.
 - ii. Copy the IBC Office on the Continuing Review of Research Form and associated documents (e.g., consent forms) submitted to the IRB on an annual basis.

- iii. Copy the IBC Office on all amendments submitted to the IRB.
 - iv. Verification from OBA of annual report submission should be copied to the IBC office.
 - v. Copy the IBC Office on Adverse Events reported to the IRB for research involving human gene transfer.
 - vi. Submission of safety reports to OBA by PI or delegated sponsor.
 - Any serious adverse event that is both unexpected and associated with the use of the gene transfer product.
 - Any finding from tests in laboratory animals that suggests a significant risk for human research participants including reports of mutagenicity, teratogenicity, or carcinogenicity.
 - Time Frames for reporting and information to be contained in the report can be found in Appendix M of the *NIH Guidelines*.
 - vii. Copy the IBC Office on all safety reports received from sponsor.
6. Submit significant modifications to the IBC prior to initiation of the changes to the protocol. Significant modifications include, but are not limited to, any change in review category, changes in biosafety level, changes requiring additional approvals and any change involving research in section I of Application for the Use of Recombinant DNA in Research- Form A. Questions regarding modifications should be directed to the IBC Office.