Institutional Responsibilities under the *NIH Guidelines*

- **The Institution shall:**
  - **Establish and implement policies for the safe conduct of recombinant DNA research**
  - **Establish an Institutional Biosafety Committee**
  - **Assist and ensure compliance with the *NIH Guidelines* by investigators**
  - **Ensure appropriate training for IBC members and staff, PIs, laboratory staff**

Institutional Responsibilities under the *NIH Guidelines* (continued)

- **The Institution shall:**
  - **Determine necessity for health surveillance of personnel involved in recombinant DNA research**
  - **Report any significant accidents, incidents or violations of the *NIH Guidelines* to OBA within 30 days**

PI Responsibilities under the *NIH Guidelines*

PIs are responsible for full compliance with the *NIH Guidelines* during the conduct of recombinant DNA research.

PI Responsibilities under the *NIH Guidelines* (continued)

- **Investigators should:**
  - **Be adequately trained in good microbiological techniques**
  - **Provide laboratory research staff with protocols describing potential biohazards and necessary precautions**
  - **Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety and (ii) the procedures for dealing with accidents**

PI Responsibilities under the *NIH Guidelines* (continued)

- **Investigators should:**
  - **Inform the laboratory staff of the reasons and provisions for any precautionary medical practices (e.g. vaccinations)**
  - **Supervise laboratory staff to ensure that required safety practices and techniques are employed**
  - **Correct work errors and conditions that may result in the release of recombinant DNA material**

PI Responsibilities under the *NIH Guidelines* (continued)

- **Investigators should:**
  - **Comply with permit and shipping requirements for recombinant DNA molecules**

PI Responsibilities When Conducting Human Gene Transfer Research

- **PIs conducting research subject to section III-C of the *NIH Guidelines* (Human Gene Transfer) have a number of additional responsibilities that are outlined in Appendix M of the *NIH Guidelines:***
  - **Ensure all aspects of Appendix M have been appropriately addressed prior to submission of a human gene transfer experiment to NIH OBA for review by the RAC**

PI Responsibilities When Conducting Human Gene Transfer Research (cont'd)

- **Provide a letter signed by the PI(s) on institutional letterhead acknowledging the documentation being submitted to NIH OBA complies with the requirements set forth in Appendix M**
- **Not enroll research participants in a human gene transfer experiment until the RAC review process is completed; IBC approval has been obtained; IRB approval has been obtained; and all applicable regulatory authorizations have been obtained**
- **Comply with reporting requirements for human gene transfer experiments.**

PI Responsibilities for Incident Reporting

PIs must report any significant problems pertaining to the operation of implementation of containment practices and procedures, violations of the NIH Guidelines, or any significant research related accidents and illnesses to the IBC, NIH OBA, and, as applicable, the Biological Safety Officer, Greenhouse or Animal Facilities Director, and other appropriate authorities.

More Information

- **Further information about requirements under the *NIH Guidelines* can be obtained from the NIH Office of Biotechnology Activities**

http://oba.od.nih.gov