

Appendix J

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NIH Oversight of Research Involving Recombinant Biosafety Issues

The NIH locus for oversight of recombinant DNA research is the OBA, which is located within the Office of Science Policy, in the Office of the Director of the NIH. The OBA implements and manages the various oversight tools and information resources that NIH uses to promote the science, safety and ethics of recombinant DNA research. The key tools of biosafety oversight are the *NIH Guidelines*, IBCs, and the RAC. The NIH also undertakes special initiatives to promote the analysis and dissemination of information key to our understanding of recombinant DNA, including human gene transfer research. These initiatives include a query-capable database and conferences and symposia on timely scientific, safety, and policy issues. The NIH system of oversight is predicated on ethical and scientific responsibilities, with goals to promote the exchange of important scientific information, enable high-quality research, and help advance all fields of science employing recombinant DNA.

The *NIH Guidelines* promote safe conduct of research involving recombinant DNA by specifying appropriate biosafety practices and procedures for research involving the construction and handling of either recombinant DNA molecules or organisms and viruses that contain recombinant DNA. Recombinant DNA molecules are defined in the *NIH Guidelines* as those constructed outside of a living cell by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell. The *NIH Guidelines* are applicable to all recombinant DNA work at an institution that receives any funding from the NIH for recombinant DNA research. Compliance with the *NIH Guidelines* is mandatory for investigators conducting recombinant DNA research funded by the NIH or performed at or sponsored by any public or private entity that receives any NIH funding for recombinant DNA research. This broad reach of the *NIH Guidelines* is intended to instill biosafety practices throughout the institution, which is necessary if the practices are to be effective.

The *NIH Guidelines* were first published in 1976 and are revised as technological, scientific, and policy developments warrant. They outline the roles and responsibilities of various entities associated with recombinant DNA research, including institutions, investigators, biological safety officers, and the NIH (see Section IV of the *NIH Guidelines*). They describe four levels of biosafety and containment practices that correspond to the potential risk of experimentation and require different levels of review for recombinant DNA research, based on the nature and risks of the activity. These include:

1. Review by the RAC, and approval by the NIH Director and the IBC.
2. Review by the NIH OBA and approval by the IBC.

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3. Review by the RAC and approvals by the IBC and Institutional Review Board.
4. Approval by the IBC prior to initiation of the research.
5. Notification of the IBC simultaneous with initiation of the work.

See Section III of the *NIH Guidelines* for additional details. In all instances, it is important to note that review by an IBC is required.

The federally mandated responsibilities for an IBC are articulated solely in the *NIH Guidelines*. Their membership, procedures, and functions are outlined in Section IV-B-2. Institutions, ultimately responsible for the effectiveness of IBCs, may define additional roles and responsibilities for these committees in addition to those specified in the *Guidelines*. To access the *NIH Guidelines* see the following website:
www4.od.nih.gov/oba/rac/guidelines/guidelines.html

The RAC is a panel of national experts in various fields of science, medicine, genetics, and ethics. It includes individuals who represent patient perspectives. The RAC considers the current state of knowledge and technology regarding recombinant DNA research and advises the NIH Director and OBA on basic and clinical research involving recombinant DNA and on the need for changes to the *NIH Guidelines*.

Additional information on OBA, the *NIH Guidelines*, and the NIH RAC can be found at:
<http://www4.od.nih.gov/oba/>.