

Compliance with The NIH Guidelines for Research Involving Recombinant DNA Molecules

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Key Dates

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Office of Biotechnology Activities (OBA), (<http://www4.od.nih.gov/oba/>)

The NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) stipulate biosafety and containment measures for recombinant DNA research. Furthermore, they outline essential ethical principles and key safety reporting requirements for human gene transfer research.

Investigators and institutions are reminded that they must adhere to the NIH Guidelines when they perform research involving recombinant DNA molecules that is conducted at, or sponsored by, an entity receiving any NIH support for recombinant DNA research. Therefore, even privately funded projects employing recombinant DNA must adhere to the NIH Guidelines if they are being carried out at, or funded by, an organization that has any NIH contracts, grants, or other support for this kind of research. A fully indexed and easily navigated version of the NIH Guidelines can be accessed at:

<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

Institutional Biosafety Committees - Institutions subject to the NIH Guidelines must establish an Institutional Biosafety Committee (IBC) for the review of recombinant DNA research. Each institution must register the IBC with the NIH Office of Biotechnology Activities (OBA). Furthermore, membership updates must be filed annually with OBA. Unless exempted from the NIH Guidelines, experiments involving recombinant DNA must at a minimum be registered with the IBC, and certain types of experiments require IBC review and approval prior to initiation (including, but not limited to, all human gene transfer studies). More information on the NIH Guidelines and IBCs, including the registration and annual reporting requirements, can be found at:

<http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm>

Requirements for human gene transfer trials - Investigators conducting human gene transfer research at, or sponsored by, an institution that receives NIH support for recombinant DNA research must comply with Appendix M of the NIH Guidelines.

Appendix M outlines points to consider in the design and submission of these protocols to OBA. Under Appendix M, investigators conducting trials subject to the NIH Guidelines must register their protocols with OBA and provide certain information about the trials for review by the NIH and, possibly, the NIH Recombinant DNA Advisory Committee. Once a trial is initiated, further information must be submitted to NIH, including reports of serious adverse events (SAEs). Investigators must report in an expedited manner those SAEs that are unexpected and possibly associated with the gene transfer product.

These reports should be sent to OBA within 15 calendar days of sponsor notification, unless the event was life-threatening or fatal, in which case, it should be reported within 7 calendar days. More information about Appendix M requirements can be found in "Frequently Asked Questions" at: http://www4.od.nih.gov/oba/RAC/RAC_FAQs.htm

Investigators are encouraged to report adverse events using the NIH Genetic Modification Clinical Research Information System (GeMCRIS). This system provides an online reporting format enabling the creation of reports that can be submitted electronically to the NIH and that can be conveyed to the FDA and the institutional oversight committees that may need to review them (see below). More about using GeMCRIS for on-line reporting can be found at: <http://www4.od.nih.gov/oba/RAC/GeMCRIS/GeMCRIS.htm>

Investigators and administrators are encouraged to contact OBA with any questions they may have concerning these and other requirements. Questions can be directed to:

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