Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules

Information for NIH Intramural Investigators:
Notice of NIH Guidelines Compliance and Recent Changes

May 28, 2002

National Institutes of Heath Office of Biotechnology Activities

NIH intramural investigators are reminded that they must adhere to the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) when they perform research involving recombinant DNA. Adherence to the NIH Guidelines is mandatory and important because they stipulate biosafety and containment measures for recombinant DNA research. Furthermore, they delineate critical ethical principles and outline key safety reporting requirements for human gene transfer research. A fully indexed, hyperlinked copy of the NIH Guidelines can be viewed on line or downloaded at:
https://auth.osp.od.nih.gov/sites/default/files/resources/NIH_Guidelines.pdf

Reporting safety information from human trials - NIH intramural investigators conducting human gene transfer research must comply with Appendix M of that document. Appendix M outlines points to consider in the design and submission of these protocols to OBA. Reporting serious adverse events and other safety information is a key aspect of compliance with that Appendix. The scope and timing of safety reports were recently modified to be harmonized with those of the FDA, and now the same information can be reported to both agencies on the same schedule. Investigators conducting human gene transfer research subject to the NIH Guidelines must report in an expedited manner those serious adverse events that are unexpected and possibly associated with the gene transfer product. These reports should be sent to OBA and the NIH Institutional Biosafety Committee (through the Safety Operations Section in the Division of Safety (forms available by calling Ext. 6-2346) 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. All other serious adverse events should be reported on an annual basis. More information about these requirements can be found at:
http://osp.od.nih.gov/office-biotechnology-activities

Investigators and administrators are encouraged to contact Safety Operations Section in the Division of Safety (Ext. 6-2346), their Safety and Health Specialist or OBA with any questions they may have about these and other requirements. Questions for OBA can be directed to:

Allan C. Shipp
Director of Outreach
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750, MSC 7985
Bethesda, Maryland 20892
301-435-2152
Email: oba@od.nih.gov

Also, readers may wish to subscribe to OBA's listserv to stay apprised of developments in this arena. Send the message "subscribe oba_news" to listserv@list.nih.gov