



Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985
(301) 496-9838 (Phone)
(301) 496-9839 (Fax)
<http://www4.od.nih.gov/oba/>

December 6, 2004

TO: All Institutions Receiving NIH Funding

FROM: Amy P. Patterson, M.D. *AP*
Director
NIH Office of Biotechnology Activities

SUBJECT: Recombinant DNA Research and Institutional Biosafety Committees

The purpose of this memorandum is to remind NIH grant recipients of the importance of biosafety review and oversight for research involving recombinant DNA. This is a matter whose significance is enhanced as many institutions are undertaking new programs of research related to biodefense and emerging infectious disease threats, which often involve recombinant DNA technologies and require stringent attention to the proper containment of highly pathogenic organisms.

When institutions receive NIH funding for research involving recombinant DNA molecules, they must follow the provisions for containment and biosafety oversight set forth in the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*. Compliance with the *NIH Guidelines* is mandatory; failure to adhere to the *NIH Guidelines* can result in suspension or termination of NIH funding for this type of research or lead to a requirement for prior NIH approval of any or all recombinant DNA projects at the institution. Further, compliance with the *NIH Guidelines* is critical to the safe conduct of research and to the fulfillment of an institutional commitment to the protection of staff, the environment, and public health.

In the coming year, the NIH will be conducting site visits at selected institutions to obtain further information on IBC compliance with the *NIH Guidelines* and to educate institutions more directly about requirements that apply to the conduct of recombinant DNA research. In the meantime, institutions are strongly encouraged to take stock of the portfolio of recombinant DNA research they are conducting and to verify that research projects are being registered and, as appropriate, approved by a duly-constituted Institutional Biosafety Committee (IBC).

Section IV-B-2 of the *NIH Guidelines* requires institutions to establish an IBC to review research subject to the *NIH Guidelines* and to oversee investigator compliance with the biosafety and reporting requirements set forth in the *NIH Guidelines*. Institutions must ensure that their IBCs are properly constituted and functioning in full compliance with the *NIH Guidelines*.

Compliance includes:

- Registering the IBC with the NIH Office of Biotechnology Activities; the registration must include (1) a roster of IBC members indicating their principal role on the committee (e.g., chair, contact person, expert in areas identified by the *NIH Guidelines*) and (2) biosketches of committee members. Biosketches should reflect the professional background and perspective of the individual. Preferably, these documents should not include private personal information (e.g., home address, Social Security Number);
- Filing a report at least annually that updates the committee roster and biosketches; and
- Ensuring that the IBC fulfills all the administrative, oversight, review and reporting functions described in Sections IV-B-2-a and IV-B-2-b of the *NIH Guidelines*.

The *NIH Guidelines* are accessible on the Internet at:

<http://www4.od.nih.gov/oba/IBC/IBCnihguidelines.htm>. Section III of the *NIH Guidelines* describes categories of experiments subject to the *NIH Guidelines* and the attendant levels of IBC notification and review. The definition of recombinant DNA is found in Section I-B. Experiments exempted from the *NIH Guidelines* are listed in Section III-F. OBA is pleased to assist with any questions concerning proper interpretation and implementation of the *NIH Guidelines*.

More information about IBCs - including Frequently Asked Questions, slide presentations, and video of training sessions - can be found on OBA's Web site at

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

If you have questions about requirements associated with the *NIH Guidelines*, please contact Allan C. Shipp, Director of Outreach, at 301-435-2152 or at shippa@od.nih.gov