DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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/

February 23, 2007

TO: Members and Staff of Institutional Biosafety Committees

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

SUBJECT: Guidance on the Content of Minutes of Institutional Biosafety Committee Meetings

In May 2004, the NIH Office of Biotechnology Activities (OBA) issued guidance concerning the preparation of, and public access to, minutes of Institutional Biosafety Committee meetings (available at http://www4.od.nih.gov/oba/IBC/IBC_Minute_Q_A.pdf). The purpose of the present guidance is to elaborate further on appropriate content of IBC meeting minutes and the level of detail they should contain.

The *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) accord institutions latitude in the development of specific IBC administrative procedures and practices, including those regarding the preparation of minutes. That latitude notwithstanding, OBA expects IBCs to document adequately fulfillment of their review and oversight responsibilities described in Section IV-B-2-b of the *NIH Guidelines*.

Section IV-B-2-b describes a number of activities that the IBC must carry out on behalf of the institution including:

- Conducting an assessment of the containment levels required by the *NIH Guidelines* when reviewing proposed research;
- Assessing the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research; and
- Periodically reviewing recombinant DNA research to ensure compliance with the *NIH Guidelines*.

With respect to the review of proposed recombinant DNA research, the *NIH Guidelines* cite a number of matters that IBCs should consider as appropriate. These matters are described in Section II-A-3 and Section III of the *NIH Guidelines* and include:

- Agent characteristics (e.g. virulence, pathogenicity, environmental stability)
- Types of manipulations planned
- Source(s) of the inserted DNA sequences (e.g., species)
- Nature of the inserted DNA sequences (e.g., structural gene, oncogene)
- Host(s) and vector(s) to be used

- Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced
- Containment conditions to be implemented
- Applicable section of the *NIH Guidelines* (e.g., Section III-D-1, Section III-E-1, etc.)

In general, the IBC meeting minutes should offer sufficient detail about the discussion of these matters to document the committee's rationale for particular decisions.

The NIH system of oversight for recombinant DNA research described in the *NIH Guidelines* is based on expectations of transparency and public access to information about recombinant DNA research activities. Institutions should prepare IBC meeting minutes that not only serve the institution's need for a record of the IBC's proceedings, but that also document for NIH and the public that the IBC is fulfilling the performance expectations of the *NIH Guidelines*.

Questions about this guidance can be addressed to OBA by email to oba@od.nih.gov or by telephone at 301-496-9838.