House of Representatives Report No. 94-1005

"Health Research and Health Services Amendments of 1976"

"(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of the National Institutes of Health. SEC. 205. Subsection (c) of section 473 is amended by striking out "March 31" and inserting in lieu thereof "September 30".

TITLE III-DISCLOSURE OF RESEARCH INFORMATION

SEC. 301. (a)(1) The President's Biomedical Research Panel (established by section 201(a) of the National Cancer Act Amendments of 1974 (Public Law 93-352)) and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (established by section 201 of the National Research Act (Public Law 93-348)) shall each conduct an investigation and study of the implication of the disclosure to the public of information contained in research protocols, research hypotheses, and research designs obtained by the Secretary of Health, Education, and Welfare (hereinafter in the subsection referred to as the "Secretary") in connection with an application or proposal submitted, during the period beginning January 1, 1975, and ending December 31, 1975, to the Secretary for a grant, fellowship, or contract under the Public Health Service Act. In making such investigation and study the Panel and the Commission shall each determine the following:

(A) The number of requests made to the Secretary for the disclosure of information contained in such research protocols, hypotheses, and designs and the interests represented by the persons for whom such

requests were made.

(B) The purposes for which information disclosed by the Secretary

pursuant to such requests was used.

(C) The effect of the disclosure of such information oni) proprietary interests in the research protocol, hypothesis, or design from which such information was disclosed and on

(ii) the ability of peer review systems to insure high quality patent rights;

federally funded research; and (iii) the (I) protection of the public against research which presents an unreasonable risk to human subjects of such research and (II) the adequacy of informed consent procedures.

(2) (A) Not later than May 31, 1976, the Panel shall complete the investigation and study required to be made by the Panel by paragraph (1), and, not later than June 30, 1976, the Panel shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations

for legislation as the Panel deems appropriate.
(B) Not later than November 30, 1976, the Commission shall complete the investigation and study required to be made by the Commission by paragraph (1), and, not later than December 31, 1976, the Commission shall submit to the Committee on Interstate and Foreign Commerce of the House of Representatives and the Committee on Labor and Public Welfare of the Senate a report on such investigation and study. The report shall contain such recommendations for legislation as the Commission decms appropriate.

(b) Section 211(b) of the National Research Act (Public Law 93-348) is amended by striking out "July 1, 1976" and inserting in lieu thereof

"January 1, 1977".