FOIA Request

## NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH

### Meeting

Notice is hereby given that the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research will meet on January 7 and 8, 1977, in Conference Room 6, C Wing, Building 31, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland. The meeting will convene at 9:00 a.m. each day and will be generally open to the public, subject to the limitations of available space. Topics identified in the mandate to the Commission under the National Research Act (Pub L. 93-348), as amended, including psychosurgery and the participation of children in research, will be the agenda for this meeting.

The National Commission is required under recently enacted legislation to study and make recommendations for legislation to Congress on the topic of public disclosure, pursuant to the Freedom of Information Act, of information contained in research protocols, hypotheses and designs obtained by the Secretary of DHEW in connection with applications or proposals for grants, fellowships and contracts under the Public Health Service Act. Specifically, title III of the Health Research and Health Services Amendments of 1976 (Pub. L. 94-278) provides in part that

> the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (established by section 202 of the National Research Act (Public Law 93-348) shall * * * 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 Commission shall * * * determine the following:
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> (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.
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> (B) The purposes for which information disclosed by the Secretary pursuant to such requests was used.
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> (C) The effect of the disclosure of such information on—
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> (i) proprietary interest in the research protocol, hypothesis, or design from which such information was disclosed and patent rights;
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> (ii) the ability of peer review systems to insure high quality federally funded research; and
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> (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.

To assist in its study, the National Commission desires to have written statements from interested parties, including researchers who may be affected by disclosure of research information. Statements should be received not later than January 28, 1977, in order to be of assistance to the Commission in their discussion of this topic at the meeting scheduled for February 11-12, 1977. Writers are encouraged to include discussion of the following issues:

1. What is the narrowest exemption from disclosure of research information contained in applications or proposals submitted under the Public Health Service Act that is necessary to protect scientists' ideas, "stock in trade," from plagiarism; to encourage detailed and high quality grant applications; to protect patent and other proprietary interests; to prevent harm to the public resulting from the premature disclosure of preliminary research data; and to foster the frank and critical peer review necessary to insure continued high quality federally funded research?

2. How should the purposes of exemption from disclosure, described in the first question above, be balanced against such purposes of disclosure of research information as protection of human subjects in clinical research against unreasonable risk and openness of governmental decision making?

3. Can the basic research idea of a proposal or application submitted under the Public Health Service Act be separated out for the purpose of exempting it from disclosure for a period of time? Would exemption for a period of time serve to protect the proprietary interests and patent rights of the investigator? Should any limitation be stipulated for all research or for only clinical research?

4. Is it possible to predict which categories of proposals or applications have potential patent implications?

Comments should be addressed to the National Commission for the Protection of Human Subjects, 5333 Westbard Avenue, Room 125, Bethesda, Maryland 20016. Requests for information and for copies of a legal analysis of the disclosure issue that was prepared for the National Commission should be directed to Ms. Anne Ballard (301) 496-7775, at the same address.

Dated: December 20, 1976.

CHARLES U. LOWE,
*Executive Director, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.*

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