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National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: Research on the Fetus

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NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH: RESEARCH ON THE FETUS

RECOMMENDATIONS

1. Therapeutic research directed toward the fetus may be conducted or supported, and should be encouraged, by the Secretary, DHEW, provided such research (a) conforms to appropriate medical standards, (b) has received the informed consent of the mother, the father not dissenting, and (c) has been approved by existing review procedures with adequate provision for the monitoring of the consent process. (Adopted unanimously.)

2. Therapeutic research directed toward the pregnant woman may be conducted or supported, and should be encouraged, by the Secretary, DHEW, provided such research (a) has been evaluated for possible impact on the fetus, (b) will place the fetus at risk to the minimum extent consistent with meeting the health needs of the pregnant woman, (c) has been approved by existing review procedures with adequate provision for the monitoring of the consent process, and (d) the pregnant woman has given her informed consent. (Adopted unanimously.)

3. Nontherapeutic research directed toward the pregnant woman may be conducted or supported by the Secretary, DHEW, provided such research (a) has been evaluated for possible impact on the fetus, (b) will impose minimal or no risk to the well-being of the fetus, (c) has been approved by existing review procedures with adequate provision for the monitoring of the consent process, (d) special care has been taken to assure that the woman has been fully informed regarding possible impact on the fetus, and (e) the woman has given informed consent. (Adopted unanimously.)

It is further provided that nontherapeutic research directed at the pregnant woman may be conducted or supported (f) only if the father has not objected, both where abortion is not at issue (adopted by a vote of 8 to 1) and where an abortion is anticipated (adopted by a vote of 5 to 4).

4. Nontherapeutic research directed toward the fetus *in utero* (other than research in anticipation of, or during, abortion) may be conducted or supported by the Secretary, DHEW, provided (a) the purpose of such research is the development of important biomedical knowledge that cannot be obtained by alternative means, (b) investi-

gation on pertinent animal models and nonpregnant humans has preceded such research, (c) minimal or no risk to the well-being of the fetus will be imposed by the research, (d) the research has been approved by existing review procedures with adequate provision for the monitoring of the consent process, (e) the informed consent of the mother has been obtained, and (f) the father has not objected to the research. (Adopted unanimously.)

5. Nontherapeutic research directed toward the fetus in anticipation of abortion may be conducted or supported by the Secretary, DHEW, provided such research is carried out within the guidelines for all other nontherapeutic research directed toward the fetus *in utero*. Such research presenting special problems related to the interpretation or application of these guidelines may be conducted or supported by the Secretary, DHEW, provided such research has been approved by a national ethical review body. (Adopted by a vote of 8 to 1.)

6. Nontherapeutic research directed toward the fetus during the abortion procedure and nontherapeutic research directed toward the nonviable fetus *ex utero* may be conducted or supported by the Secretary, DHEW, provided (a) the purpose of such research is the development of important biomedical knowledge that cannot be obtained by alternative means, (b) investigation on pertinent animal models and nonpregnant humans (when appropriate) has preceded such research, (c) the research has been approved by existing review procedures with adequate provision for the monitoring of the consent process, (d) the informed consent of the mother has been obtained, and (e) the father has not objected to the research; and provided further that (f) the fetus is less than 20 weeks gestational age, (g) no significant procedural changes are introduced into the abortion procedure in the interest of research alone, and (h) no intrusion into the fetus is made which alters the duration of life. Such research presenting special problems related to the interpretation or application of these guidelines may be conducted or supported by the Secretary, DHEW, provided such research has been approved by a national ethical review body. (Adopted by a vote of 8 to 1.)

7. Nontherapeutic research directed toward the possibly viable infant may be conducted or supported by the Secretary, DHEW, provided (a) the purpose of such research is the development of important biomedical knowledge that cannot be obtained by alternative means, (b) investigation on pertinent animal models and nonpregnant humans (when appropriate) has preceded such research, (c) no additional risk to the well-being of the infant will be imposed by the research, (d) the

research has been approved by existing review procedures with adequate provision for the monitoring of the consent process, and (e) informed consent of either parent has been given and neither parent has objected. (Adopted unanimously.)

8. Review Procedures. Until the Commission makes its recommendations regarding review and consent procedures, the review procedures mentioned above are to be those presently required by the Department of Health, Education, and Welfare. In addition, provision for monitoring the consent process shall be required in order to ensure adequacy of the consent process and to prevent unfair discrimination in the selection of research subjects, for all categories of research mentioned above. A national ethical review, as required in Recommendations (5) and (6), shall be carried out by an appropriate body designated by the Secretary, DHEW, until the establishment of the National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research. In order to facilitate public understanding and the presentation of public attitudes toward special problems reviewed by the national review body, appropriate provision should be made for public attendance and public participation in the national review process. (Adopted unanimously, one abstention.)

9. Research on the Dead Fetus and Fetal Tissue. The Commission recommends that use of the dead fetus, fetal tissue and fetal material for research purposes be permitted, consistent with local law, the Uniform Anatomical Gift Act and commonly held convictions about respect for the dead. (Adopted unanimously, one abstention.)

10. The design and conduct of a nontherapeutic research protocol should not determine recommendations by a physician regarding the advisability, timing or method of abortion. (Adopted by a vote of 6 to 2.)

11. Decisions made by a personal physician concerning the health care of a pregnant woman or fetus should not be compromised for research purposes, and when a physician of record is involved in a prospective research protocol, independent medical judgment on these issues is required. In such cases, review panels should assure that procedures for such independent medical judgment are adequate, and all conflict of interest or appearance thereof between appropriate health care and research objectives should be avoided. (Adopted unanimously.)

12. The Commission recommends that research on abortion techniques continue as permitted by law and government regulation. (Adopted by a vote of 6 to 2.)

13. The Commission recommends that attention be drawn to Section 214(d) of the National Research Act (P.L. 93–348) which provides that:

> "No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part by the Secretary of Health, Education, and Welfare if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions."
> (Adopted unanimously.)

14. No inducements, monetary or otherwise, should be offered to procure an abortion for research purposes. (Adopted unanimously.)

15. Research which is supported by the Secretary, DHEW, to be conducted outside the United States should at the minimum comply in full with the standards and procedures recommended herein. (Adopted unanimously.)

16. The moratorium which is currently in effect should be lifted immediately, allowing research to proceed under current regulations but with the application of the Commission's Recommendations to the review process. All the foregoing Recommendations of the Commission should be implemented as soon as the Secretary, DHEW, is able to promulgate regulations based upon these Recommendations and the public response to them. (Adopted by a vote of 9 to 1.)