AAP Code of Ethics for the Use of Fetuses and Fetal Material for Research

Research on the fetus and newborn is of the greatest importance in contributing to the health and welfare of the entire population. Such research, motivated by humane concern, should be continued and fostered, subject to adequate and clearly defined safeguards.*

The American Academy of Pediatrics recognizes that through research involving previable fetuses, new knowledge may be gained which would ultimately benefit viable infants. The American Academy of Pediatrics also recognizes that some of these areas of research, while not jeopardizing the health and welfare of the fetus, are not of direct benefit to that particular fetus. In such cases express consent should be obtained from the parent. "The whole previable fetus has offered an important opportunity that cannot be obtained in any other way for making observations of great value on the transfer of substances across the human placenta, the reaction of the immature fetus to drugs, and on the endocrinological development of the fetus and the development of the placenta."1

Research activities involving the fetus in utero or pregnant women may be undertaken for the purpose of benefiting that particular fetus or to respond to the health needs of the mother,2 as part of the procedure to terminate the pregnancy, and for the purpose of evaluating or improving methods of prenatal diagnosis, methods of prevention of premature birth, or methods of intervention to offset the effects of genetic abnormality or congenital injury or to ascertain the safety and efficacy to the fetus of drugs which might be needed by pregnant women.2

For the purposes of this code of recommendations, the following definitions have been accepted:

Viability of the fetus means the ability of the fetus, after either spontaneous or induced delivery, to survive (given the benefit of medical therapy) to the point of independently maintaining heart beat and respiration. If the fetus has this ability, it is viable and therefore a premature infant.

Abortus means a fetus when it is expelled whole, prior to viability, whether spontaneously or as a result of medical or surgical intervention. The term does not apply to the placental fetal material which is macerated at the time of expulsion; or cells, tissue, or organs excised from a dead fetus.3

Because of the rapid changes taking place in medical knowledge, the definition of viability should be reviewed regularly in order that it be consistent with these rapid changes.

Determination of viability entails a subjective and objective judgment by the physician attending labor or examining the product of conception, and must be made by a physician other than the investigator wishing to use fetal tissue in research. In general, and all other circumstances notwithstanding, a beating heart alone is not sufficient evidence of viability. At least one additional necessary condition is the possibility that the lungs can be inflated. Without this precondition, no currently available mechanisms to initiate or

maintain respiration can sustain life; and in this case, though the heart is beating, the fetus or abortus is in fact nonviable.4

CODE

(1) Research on the fetus in utero (where delivery of a previable fetus is not contemplated): Investigations and tests may be carried out with the intention of benefiting the mother, her expected child, or both. For these investigations and tests, informed consent should be obtained.

(2) Research on the viable fetus: When the fetus is viable after delivery, the ethical obligation is to sustain its life so far as possible. It is both unethical and illegal to carry out any experiments which are inconsistent with treatment necessary to promote the life of the fetus. It is recognized that in many instances the techniques used to aid a distressed fetus may be so new that in some degree they may be considered experimental.

(3) Research on the previable fetus in utero (where abortion is planned) or abortus: This research is permissible providing: (a) animal studies, if appropriate, have been completed; (b) the mother and father are legally competent and have given their consent, except that the father's consent need not be secured if his identity or whereabouts cannot reasonably be ascertained; (c) individuals engaged in the research will have no part in: (1) any decisions as to the timing, method, or procedures used to terminate the pregnancy, and (2) evaluating the viability of the fetus at the termination of the pregnancy; (d) such research is only carried out in departments directly related to a medical institution and with the express sanction of its committee on human experimentation; (e) before permitting such research the committee on human experimentation satisfy itself: (1) on the validity of the research; (2) that the required information cannot be obtained in any other way, and (3) that the investigators have the necessary facilities, skill, and integrity; (f) dissection of the dead fetus or experiments on the fetus or fetal material do not occur in the operating theatre or place of delivery; (g) there is no monetary exchange for fetuses or fetal material; (h) full records are kept by the relevant institution.

(4) Research on the dead fetus or abortus: This research is permissible provided the conditions in paragraph 3 (b to h) above are observed and the research conducted in accordance with any applicable state or local laws governing autopsy.

If the abortus is an organ or tissue donor, the research shall be conducted in accordance with any applicable state or local laws governing transplantation or anatomical gifts.

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REFERENCES
AAP Code of Ethics for the Use of Fetuses and Fetal Material for Research: Task Force on Pediatric Research, Informed Consent and Medical Ethics
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