May 17, 2001

Protection of Human Research Subjects: Summary of Clinton Admin. Changes

The Clinton Administration's January 17, 2001 changes to the Human Research Subjects regulations at 45 CFR 46 includes the following changes:

RESEARCH PROTOCOL FOR NEWBORNS AND PREGNANT WOMEN MODIFIED:

Since HEW (HHS) Secretary Caspar Weinberger's implementation of these regulations in 1975 at 40 FR 33526, the definition of a newborn's "viability" has always been tied to her ability "to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration." This aspect of the definition has not changed since 1975. Also since 1975, these regulations oddly have defined a newborn baby as a "fetus" until someone determines she will survive.

Clinton's regulation maintains this newborn as "fetus" definition and establishes three different categories of newborns: 1) "fetuses" of uncertain viability; 2) nonviable "fetuses"; and 3) viable "fetuses"[see chart #1]. Clinton's regulation also outlines new protocols for pregnant moms to be in many types of research, whereas previously pregnant moms were mostly prohibited and excluded from research other than research necessary for the mother's or the unborn baby's health [see chart #2]. Clinton's regulation also adds part (b) to research on dead fetuses which says if living individual (like the mother or father) of the dead baby can be identified, than living individuals are considered research subjects (which may mean they need to give consent for research on their baby's corpse) [see chart #3].

PARENTAL CONSENT REQUIREMENTS:

The informed parental consent requirement is applicable to research conducted before and after delivery. Clinton's regulation further requires that the authorizing parties to the research, either the parents together or the woman alone, be fully informed of the "reasonably foreseeable impact" of research on their baby (both born and unborn).

Under Clinton's regulation, the parental consent requirement has been modified from the previous requirement of the consent of both parents for research on pregnant mothers to now merely the consent of the woman. Clinton's regulation strikes paternal consent in order to permit pregnant women to participate in clinical trials that would meet the requirements of § 46.204. For instance, to participate in AIDS research, that by law must be confidential, the pregnant mom no longer will need to seek the baby's father's consent. Not until after the baby is delivered, is the father's consent considered authorized informed consent under §§ 46.204(e) and 46.205(b)(2). The Clinton regulation also requires one parent's consent for research conducted on "fetuses" (newborns) of uncertain viability and both parents' consent for research on nonviable "fetuses" (newborns).

OVERSIGHT REQUIREMENTS RELAXED:

Under Clinton's regulation, Ethical Advisory Boards, which were said to be composed of individuals "competent to deal with medical, legal, social, ethical, and related issues," are removed from the research oversight process in compliance with the 1993 NIH Reauthorization Act. This occurs without modifying the duties of the Institutional Review Board (IRB), the other oversight body, thus seemingly leaving a gap in the regulations as to who determines the "ethical acceptability" of a research proposal and who monitors informed consent procedures.

NOTE: To see an analysis of the entire document, from inception to present, see the RSC spreadsheet on the history of this regulation.