

MAR 8 - 1994

ALL AGREEMENT STATES

REVIEW OF FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS (SP-94-036)

Enclosed for your information is a copy of a Presidential Memorandum to the Vice President and the Heads of Executive Departments and Agencies dated February 17, 1994, addressing the Review of Federal Policy for the Protection of Human Subjects. President Clinton directs each department and agency of Government to review present practices to assure compliance with this Federal Policy and to cease immediately sponsoring or conducting any experiments involving humans that do not fully comply with the Federal Policy.

Original Signed By  
RICHARD L. BANGART

Richard L. Bangart, Director  
Office of State Programs

Enclosure:  
As stated

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THE WHITE HOUSE

WASHINGTON

February 17, 1994

MEMORANDUM FOR THE VICE PRESIDENT  
THE HEADS OF EXECUTIVE DEPARTMENTS  
AND AGENCIES

SUBJECT: Review of Federal Policy for the Protection of  
Human Subjects

Federally funded biomedical and behavioral research has resulted in major advances in health care and improved the quality of life for all Americans. The pursuit of new knowledge in these fields of research often requires experiments that involve human subjects. Although human subjects research is an essential element of biomedical and behavioral research, bioethical considerations must influence the design and conduct of such research.

Since 1947, when guidelines for research with human subjects were promulgated, there has been increasingly widespread recognition of the need for voluntary and informed consent and a scientifically valid design of experiments involving human subjects.

Over time, this recognition has evolved into a rigorous and formalized system of regulations and guidelines, which were codified in governmental policies on human subject research, and were included in the former Department of Health, Education and Welfare's regulations in 1974, 45 C.F.R. 46. In 1991, 16 agencies formally adopted the core of these regulations in a common Federal Policy for the Protection of Human Subjects. This Policy requires that all research protocols involving human subjects be reviewed by an Institutional Review Board. This review ensures that (1) risks are minimized and reasonable in relation to anticipated benefits; (2) there is informed consent; and (3) the rights and welfare of the subjects are maintained (56 Fed. Reg. 28003 (June 18, 1991)).

Although these regulations provide the framework for protecting human subjects in research, we must exercise constant care and ensure that these regulations are strictly enforced by departments and agencies. Therefore, I direct each department and agency of Government to review present practices to assure compliance with the Federal Policy for the Protection of Human Subjects and to cease immediately sponsoring or conducting any experiments involving humans that do not fully comply with the Federal Policy.

William B. Clinton



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

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