

APPENDIX D

SECRETARY OF ENERGY MEMO UPDATING THE POLICY FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH



The Secretary of Energy
Washington, DC 20585
January 20, 1998

MEMORANDUM FOR ALL DEPARTMENTAL EMPLOYEES

FROM: FEDERICIO PEÑA

SUBJECT: Update on Departmental Policy for the Protection of Human Subjects in Research

All DOE employees, contractors, and grantees must be mindful of the importance of protecting the rights and welfare of human subject research volunteers. In a world of rapidly advancing medical technology, revolutionary genetics research, and ever-increasing threats to personal privacy, the protection of human subjects in research is paramount. All research conducted at DOE, supported with DOE funds, or performed by DOE employees, including classified and proprietary, must comply with federal regulations and DOE Orders to protect human subjects. These requirements must be met before work is initiated. Responsibility for the ethical conduct of research begins with researchers, extends to their institutions and local Institutional Review Boards (IRBs), and includes DOE field and program officials.

Research using human subjects encompasses a broader range of research than many investigators, program managers, and government officials often realize. In addition to traditional biomedical and clinical studies, human subjects research includes, but is not limited to, studies that use:

- Identifiable or high risk data, including surveys, collected through direct intervention or interaction with individuals.
- Private information readily identifiable with individuals, including genetic information and medical and exposure records, such as in worker surveillance studies.

- Worker populations or subgroups.
- Humans to test devices, products, or materials developed through research; to examine human-machine interfaces; or to evaluate environmental alterations.
- Bodily materials such as cells, blood, tissues, or urine that are identifiable with individuals.

Within the Department, the Office of Energy Research is responsible for making final decisions as to what constitutes DOE-related human subject research and how human research subject protection must be implemented. Questions or uncertainties regarding the applicability of human subject protection regulations to research studies should be addressed to:

Dr. Susan L. Rose, DOE Human Subjects Protection Program Manager
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Dr. Rose should be consulted when a project is under development, if local administrative support is unable to evaluate or meet protection requirements, and when referrals to other resources are needed. The DOE Human Subjects Protection Program has a wide variety of educational and technical resources available for investigators, administrators, and IRBs.

Thank you for helping make DOE a leader in the protection of human subjects in research.