

U.S. Department of Energy  
Washington, D.C.

ORDER

DOE 1300.3

8-23-90

SUBJECT: POLICY ON THE PROTECTION OF HUMAN SUBJECTS

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1. PURPOSE. To establish the Department's responsibilities for implementing policy set forth in 10 CFR Part 745, Protection of Human Subjects.
  2. SCOPE. The provisions of this Order apply to all Departmental Elements and all contractors and subcontractors performing work for the Department, as provided by law and/or contract, and as implemented by the appropriate contracting officer. This includes non-DOE funded work at DOE-owned, -leased, or -controlled facilities.
  3. REFERENCES.
    - a. DOE 4300.2A, NON-DEPARTMENT OF ENERGY FUNDED WORK, of 12-19-86, which establishes the policy, responsibilities, and procedures for authorizing and administering non-DOE funded work performed under DOE contracts.
    - b. Title 10 CFR Part 600, DOE Financial Assistance Regulations, which provides the policies and procedures for administration and management of all DOE financial assistance activities.
    - c. Title 10 CFR Part 605, Office of Energy Research Special Research Grants Program Regulations, which provides the policies and procedures for the administration and management of basic and applied research grants awarded by the Office of Energy Research.
    - d. Title 10 CFR Part 745, Protection of Human Subjects, which sets out DOE's regulations for protection of human subjects involved in research activities.
    - e. Chapter 9 of Title 48 of the Code of Federal Regulations, Department of Energy Acquisition Regulations (DEAR), which provides the contracting policies established for DOE.
  4. BACKGROUND. In December 1981, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research recommended and proposed a uniform set of regulations, based on those of the Department of Health and Human Services, to be adopted by all Federal agencies and departments conducting human subject research. A proposed model Federal Policy for the protection of human subjects was published in

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INITIATED BY:  
Office of Energy Research

the Federal Register on November 10, 1988, establishing this uniform set of regulations as a common rule. This Order implements 10 CFR Part 745. as currently written, and at such time that it is amended to conform with the common rule.

5. DEFINITIONS.

- a. Assurance (Multiple Projects; (or) Single Project) means the written documentation, satisfactory to the Secretary of Energy, require from the prospective performing institution that assures institutional compliance with and implementation of DOE regulations for the protection of human research subjects.
- b. Certification is the official notification by the institution to DOE in accordance with the requirements of 10 CFR Part 745, that a research project or activity involving human subjects has been reviewed and approved by an Institutional Review Board in accordance with an approved assurance (see paragraph 5a).
- c. Contracting Officer is a person authorized to enter into, administer, or terminate contracts, financial assistance awards, and sales contracts and to make related determinations and findings.
- d. DOE Contractors are entities who receive awards from DOE, including management and operating contractors (M&O), which manage, operate, or provide site services to DOE research or production facilities that are principally engaged in work for the Department.
- e. DOE Facilities are any of the DOE-owned, -leased, or -controlled facilities.
- f. Field Organization is a general term for any officially established Departmental component (excludes individual duty stations) located outside the Washington, D.C., metropolitan area.
- g. Human Subject is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction"

includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

- h. Informed Consent is the legally effective consent by the human research subject, or the subject's legally authorized representative, to participate in research covered under this policy. It is obtained after providing to the subject the basic elements of informed consent as set forth in 10 CFR Part 745. Informed consent documents shall include disclosure of all potential risks and related consequences or adverse effects, 'as well as any benefits that may occur as a result of such participation.
- i. Institution is any public or private entity or agency (including Federal, State, and other agencies).
- j. Institutional Review Board (IRB) is a board or committee charged with the responsibility for review of research activities involving human subjects conducted at, or sponsored by, the institution and approved by the Department of Health and Human Services (HHS) or the DOE. The composition of the IRB and details of its procedures and responsibilities are specified in 10 CFR Part 745 and included in the multiple, single, or other project assurance.
- k. IRB Approval is the determination of the IRB that the research has been reviewed and may be conducted at an institution or facility within the constraints set forth by the IRB and by other institutional and Federal requirements.
- l. Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- m. Management and Operating Contractors are those contractors designated by the Secretary in accordance with DOE policies.

- n. Non-DOE Entities include other Federal agencies, State, regional, and local governments; educational institutions; private individuals, commercial firms, non-profit or not-for-profit organizations; international bodies; and foreign governments, individuals, firms, or organizations.
- o. Non-DOE Funded Work is any work performed for non-DOE entities that utilize DOE facilities or contractor personnel and which is not funded, wholly or in part, by DOE.
- p. Program Secretarial Officer (PSO) is a Secretarial Officer of the Department who has responsibility for research and development missions and Departmental programs.
- q. Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of this Order, whether or not they are conducted under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

6. POLICY. It is the policy of the Department of Energy that:

- a. The rights and welfare of human subjects involved in research supported or sanctioned by DOE be protected in accordance with 10 CFR 745.
- b. Until the requirements of this Order and 10 CFR 745 have been met, no research activity involving human subjects shall be initiated.

7. RESPONSIBILITIES AND AUTHORITIES.

- a. The Secretary establishes Department of Energy policy for the protection of human subjects consistent with 10 CFR 745.
- b. Director of Energy Research (ER-1) is responsible for the implementation of 10 CFR 745 within the Department in accordance with policy established by the Secretary.
- c. Associate Director for Health and Environmental Research (ER-70).
  - (1) Develops and implements procedures on the protection of human of human subjects.
  - (2) Prepares and updates guidance to be followed for obtaining approval for human subject research.

- (3) Approves all human subject assurances, negotiations, and evaluation processes. ER-70 may delegate authority for the evaluation and negotiation processes to the Heads of Field Organizations.
  - (4) Reviews all research with human subjects for compliance with DOE regulations and Orders and applicable Federal regulations. In a timely fashion, approves, rejects, or requests additional information on proposed work and provides written determination of human subject compliance to the PSO or appropriate Head of Field Organization.
  - (5) Investigates allegations of noncompliance with 10 CFR 745 and this Order, and recommends to the PSO or Head of Field Organization appropriate action required.
  - (6) Serves as the official DOE representative on the Interagency Human Subjects Coordinating Committee.
- d. Program Secretarial Officers or their Designees.
- (1) Implement the procedures established by ER-70.
  - (2) Review all proposals and applications to identify research involving human subjects.
  - (3) In accordance with procedures developed by ER-70, request determination of compliance by ER-70.
  - (4) Supply ER-70's determination of compliance with 10 CFR 745 to the cognizant contracting officer.
  - (5) Promptly notify ER-70 of known or potential adverse human health effects and issues of non-compliance in 10 CFR Part 745.
- e. Heads of Field Organizations or their Designees.
- (1) Fulfill responsibilities of PSO's under paragraph 7d for non-DOE funded work at DOE-owned or -leased facilities.
  - (2) Fulfill responsibilities of PSO's under paragraph 7d for DOE-funded work originating in the field office or Government-owned Government-operated facilities.

f. Contracting Officers.

- (1) Include in appropriate solicitations a provision requiring human subject research information in accordance with 10 CFR 745.
- (2) Require receipt of complete; assurance, certification, and ER-70 human subject-approval" documents, prior to initiation of research involving human subjects.

BY ORDER OF THE SECRETARY OF ENERGY:



JIM E. TARRO  
Director of Administration and  
Human Resource Management