

SUBJECT: PROTECTION OF HUMAN SUBJECTS

PURPOSE AND SCOPE

Research using human subjects provides important medical and scientific benefits to individuals and to society. The need for this research does not, however, outweigh the need to protect individual rights and interests. Department of Energy (DOE) policy regarding this issue is established in the Federal Policy for the Protection of Human Subjects, adopted by DOE June 18, 1991 as 10 CFR 745, *Protection of Human Subjects*. The purpose of this Policy is to establish DOE-specific policy for the protection of human subjects involved in DOE research.

POLICY

“DOE research” means all research conducted by or for DOE institutions, supported with DOE funds, or performed by DOE employees (including the National Nuclear Security Administration), whether done domestically or in an international environment, including research that is classified and proprietary. Regulations and directives that specifically address the protection of human subjects include 10 CFR Part 745, *Protection of Human Subjects*; Subparts B, C, and D of 45 CFR Part 46 (Department of Health and Human Services regulation on *Protection of Human Subjects*); and DOE O 443.1, PROTECTION OF HUMAN SUBJECTS. All applicable regulations and directives must be met before any research involving human subjects is initiated.

In addition to traditional biomedical and clinical studies, such research includes, but is not limited to, studies that accomplish the following:

- use of humans to examine devices, products, or materials with the express purpose of investigating human-machine interfaces or evaluating environmental alterations when humans are the subjects being tested;
- use of personally identifiable bodily materials, such as cells, blood, tissues, urine, or hair, even if the materials were collected previously for a purpose other than the current research;
- collection and use of personally identifiable information, such as genetic information or medical and exposure records, even if the information was collected previously for a purpose other than the current research;
- collection of personally identifiable data, including surveys or questionnaires, through direct intervention or interaction with individuals; and

- the search for generalizable knowledge about categories or classes of subjects (e.g., linking job conditions of worker populations to hazardous or adverse health outcomes).

Human subjects research does not include the following:

- studies to improve the safety or execution of routine procedures that apply to routine occupational activities;
- occupational health surveillance of individual DOE employees and DOE contractor employees to determine apparent departures from typical health status and *not* for the purpose of obtaining generalizable knowledge; and
- employee surveys used as management tools to improve worker or contractor performance as long as the identity of the participant is protected.

DELEGATION OF RESPONSIBILITY

All DOE employees, contractors, and financial assistance recipients share the responsibility to protect the rights and welfare of human research subjects. Within DOE, SC-1 is hereby delegated authority to carry out the responsibilities of the Secretary set forth in 10 CFR Part 745. This includes, but is not limited to, lead responsibility for determining what constitutes DOE-related human subjects research, ensuring that DOE keeps pace with the changing and complex nature of human subjects research, developing and implementing comprehensive DOE-wide educational programs, and performing program compliance reviews. SC-1 must be consulted about any new proposal for DOE research with human subjects *unless* a single project assurance (SPA) or multiple project assurance (MPA) from DOE SC-72 or from the Department of Health and Human Services (DHHS) has been obtained.

BY ORDER OF THE SECRETARY OF ENERGY:



T. J. GLAUTHIER
Deputy Secretary