

DATE: January 22, 2007

TO: DIRECTIVES POINTS OF CONTACT

FROM: WALTER HOWES, ACTING DIRECTOR
OFFICE OF INFORMATION RESOURCES

SUBJECT: REDLINE/STRIKEOUT OF DOE P 443.X, *Protection of Human Subjects*

In accordance with the new Directives procedures, a redline/strikeout of the Policy has been posted to RevCom to allow interested parties to see the cumulative effect of changes produced during coordination.

Draft DOE P 443.X was coordinated in RevCom beginning in August 2006. The directive writer has responded to all comments and incorporated those comments he accepted into the directive. To review the redline/strikeout, please go to <http://www.directives.doe.gov/rcLogin.html>.

Reviewing Instructions:

1. **THIS IS NOT AN OPPORTUNITY TO SUBMIT NEW COMMENTS.**
2. **Only** comments with specific objections to the changes in the Directive will be addressed.
3. Headquarters DPCs have until **February 1, 2007** to review the redline/strikeout and compile and submit comments/concurrence/nonconcurrence through RevCom.
4. Reviewers in the field are asked to meet assigned internal organizational deadlines.
5. After you have reviewed the redline/strikeout, please follow the case below that corresponds to your situation:

If you:	Then:
submitted a major comment and agree with the incorporation of your comments	go into RevCom and concur.
submitted a major comment and do not agree with the incorporation of your comments	go into RevCom, nonconcur, and submit justification for your nonconcurrence.
did not comment, but the incorporation of others' comments may have an adverse impact on your organization's mission	go into RevCom and explain how this directive will adversely impact your organization's mission.
did not comment, and are still satisfied with the directive	no action is necessary

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 Title 10 Code of Federal Regulations (CFR) 745, Protection of Human Subjects. The purpose of this Policy is to establish DOE-specific principles for the protection of human subjects involved in DOE research. **This Policy cancels and supersedes DOE P 443.1, Protection of Human Subjects, dated 5-15-2000.**

POLICY

DOE research is 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 and includes classified and proprietary research. Regulations and directives that specifically address the protection of human subjects include 10 CFR Part 745; 45 CFR Part 46, Subparts B, C, and D; Department of Health and Human Services Regulation on Protection of Human Subjects; and DOE O 443.1A, Protection of Human Subjects, dated XX-XX-06. The requirements of 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—

- use 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 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;
- collect and use 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;
- collect personally identifiable data, surveys, or questionnaires through direct intervention or interaction with individuals; and

- search for generalizable¹ knowledge about categories or classes of subjects (e.g., linking job conditions of worker populations to hazardous or adverse health outcomes).

Human subject research does not include the following:

- studies to improve the safety or execution of procedures that apply to routine occupational activities;
- occupational health surveillance of DOE Federal and 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. ~~The Secretary of Energy is responsible for the conduct of DOE-related human subjects research. The requirements for implementing this policy are described in DOE Order 443.1A (XX-XX-06) to ensure that the research program keeps pace with the changing and complex nature of human subjects research, develops and implements comprehensive educational programs, and performs program compliance reviews. Any new proposal for research with human subjects requires that the Institution administering the Institutional Review Board (IRB) for review and approval of the proposal holds a valid Federalwide Assurance (FWA) from the Department of Health and Human Services Office of Human Research Protections.~~

~~Within DOE, the Office of Science 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. The Office of Science must be consulted about any new proposal for DOE research with human subjects unless the Institution for administering the Institutional Review Board (IRB) approving for review and approval of the proposal holds a valid Federalwide Assurance from the Department of Health and Human Services Office of Human Research Protections.~~

BY ORDER OF THE SECRETARY OF ENERGY:

CLAY SELL
Deputy Secretary

¹ New information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature.

~~DOE ELEMENTS TO WHICH DOE O XXX.X IS APPLICABLE~~

~~Office of Secretary~~
~~Departmental Representative~~
~~Defense Nuclear Facilities Safety Board~~
~~National Nuclear Security Administration~~
~~Office of Chief Financial Officer~~
~~Office of Chief Information Officer~~
~~Office of Civilian Radioactive Waste Management~~
~~Office of Congressional & Intergovernmental Affairs~~
~~Office of Economic Impact and Diversity~~
~~Office of Electricity Delivery and Energy Reliability~~
~~Office of Energy Efficiency and Renewable Energy~~
~~Office of Energy Information Administration~~
~~Office of Environment, Safety, and Health~~
~~Office of Environmental Management~~
~~Office of Fossil Energy~~
~~Office of General Counsel~~
~~Office of Hearings and Appeals~~
~~Office of Human Capital Management~~
~~Office of Inspector General~~
~~Office of Intelligence and Counterintelligence~~
~~Office of Legacy Management~~
~~Office of Management~~
~~Office of Nuclear Energy, Science, and Technology~~
~~Office of Policy and International Affairs~~
~~Office of Public Affairs~~
~~Office of Science~~
~~Office of Security and Safety Performance Assurance~~
~~Bonneville Power Administration~~
~~Southeastern Power Administration~~
~~Southwestern Power Administration~~
~~Western Area Power Administration~~