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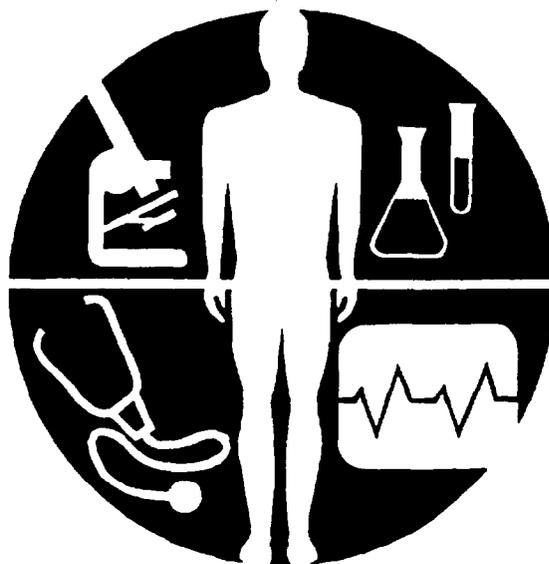
U.S. GOVERNMENT PRINTING OFFICE: 1999 454-567/00002

Protecting Human Research Subjects



within the Department of Energy

ARE YOU CONDUCTING RESEARCH USING HUMAN SUBJECTS?



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Legal requirements to protect human subjects apply to a much broader range of research than many investigators realize. In addition to covering traditional biomedical studies, legal obligations to protect human subjects also apply, for example, to research that uses—

- Human beings to test devices, products or materials that have been developed through research.
- Data collected through intervention or interaction with individuals. Intervention includes not only physical procedures (like drawing blood), but also manipulation of a subject's environment.
- Private information that can be readily identified with individuals, even if the information was not collected specifically for the study in question.
- Bodily materials such as cells, blood or urine, tissues, organs, hair, nail clippings *even if you did not collect these materials*. (Such research may be considered exempt if materials are not personally identifiable.)
- Studies conducted to gain generalizable knowledge about categories or classes of subjects such as DOE workers.
- Human beings to evaluate environmental alterations—for example, on weatherization options or habitat modifications.

IF SO, YOU MUST...

Comply with Federal regulations and U.S. Department of Energy (DOE) directives to protect human subjects.¹ These requirements apply if your research is conducted using DOE facilities or property, supported with DOE funds, or performed by DOE employees or contractors.

The Office of Science is responsible for making final decisions as to what constitutes DOE-related human subject research and how human research subject protection must be implemented.

As Stated in 10 CFR 745—

Research—a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject—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.

For proprietary or classified projects, contact DOE or your local Human Subjects Coordinator. These projects are **not** exempt from DOE Human Subjects regulations.

¹ Title 10, Code of Federal Regulations, Part 745, *Federal Policy for the Protection of Human Subjects; Notices and Rules*

Policy and Order on the Protection of Human Subjects (1999)

Order on Work for Others (Non-Department of Energy Funded Work) (1999)

For a full-text version of these orders and policy, see the DOE Directives Home Page at <http://www.explorer.doe.gov:1776/htmls/directives.html>.

The two critical areas that you must be familiar with when dealing with research involving human subject research are: **Institutional Review Boards (IRBs) and Informed Consent.**

WHAT IS THE ROLE OF THE INSTITUTIONAL REVIEW BOARD (IRB)?

The IRB at your institution must review and approve research if it involves human subjects. This process is designed to ensure that the research protects the rights and welfare of human subjects—for example, by minimizing risks, selecting subjects equitably, obtaining informed consent, and ensuring privacy and confidentiality.

IRB approval must precede initiation of any work involving human subjects. If the research continues, the IRB must review and approve the project at least once a year.

When changes occur in the procedures with human subjects, the IRB must review and approve these changes.

If human subjects are harmed, including physical injury, unexpected or adverse effects, improper disclosure of private information, economic loss, and other harmful or potentially harmful occurrences, IRB notification is required.

WHAT IF YOUR INSTITUTION HAS NO IRB?

- Establish an IRB at your institution if the number of human subject research projects justifies this step. (Obtain approval from the DOE for the newly created IRB.
- Obtain approval for your use of human subjects from an IRB elsewhere that satisfies all Federal and DOE requirements.

For more information on these options, contact the Headquarters Human Subjects Program Manager listed in the **Who to Contact** panel.

Types of IRB Review

Full Board (Convened) Review—Review of proposed research at a convened meeting at which a valid quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those members present.

Expedited Review—Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk* and for minor changes in approved research.

Exemption—Exemption from the requirement for IRB approval when it is determined that research does not involve human subjects as defined in 10 CFR 745 and/or the only involvement of human subjects is in one of the categories listed under 10 CFR 745 Sec. 101(b)(1)-(6). Human subjects regulations do not apply to exempt projects. Any research project involving human subjects thought to be exempt must be submitted to the IRB or other authority according to local procedures for determination of exempt status.

*** Minimal Risk**—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.

WHAT IS INFORMED CONSENT?

The human subjects in your project must participate willingly, having been adequately informed about the research. If the human subjects in your project are part of a vulnerable population, such as prisoners or children, special protections are required. For more information on vulnerable populations, consult the *DOE Human Subjects Handbook*, or *Protecting Human Research Subjects Institutional Review Board Guidebook* published by the Office for Protection from Research Risks (OPRR) at the National Institutes of Health.

Essentials of Informed Consent

Voluntary participation also means that subjects have enough information to give true informed consent. Essential information includes—

- **Purpose** of the research.
- **Benefits** of the research to society and, possibly, to the individual human subject.
- **All foreseeable risks or discomforts** to the subject. Note that these include not only physical injury, but also possible psychological, social, or economic harm, discomfort, or inconvenience.
- **Length of time** subject is expected to participate.
- **Person to contact** for answers to questions, or in the event of a research-related injury or emergency.
- Statement that **participation is voluntary** and that refusal to participate will not result in any penalty or any loss of benefits that the person is otherwise entitled to receive.
- **Subjects' right to withdraw** from the study at any time.

For classified research, the consent form must provide the name of the research sponsor, describe the nature of the research, and state that the research is classified.

Consent documents must be clearly written and understandable to subjects. The language must be nontechnical (comparable to the language in a newspaper or general circulation magazine), and scientific, technical, or medical terms must be plainly defined.

Informed consent, whether oral or written, may not include language that appears to waive subjects' legal rights or appears to release the investigator or anyone else from liability for negligence.

Federal Policy has been altered to strengthen the conditions under which classified research is reported to research subjects. It is important to thoroughly review and understand the most current regulations before starting research.

TO LEARN MORE...

Please refer to:

- *The DOE Human Subjects Handbook*
- *Protecting Human Subjects* newsletters
- *Protecting Human Subjects* poster
- DOE Human Subjects Program home page:

<http://www.er.doe.gov/production/ober/humsubj/index.html>

For additional guidance:

- OPRR's 1993 *Institutional Review Board Guidebook*

- OPRR Human Subjects Protections home page:

http://www.nih.gov/grants/oprr/library_human.htm

