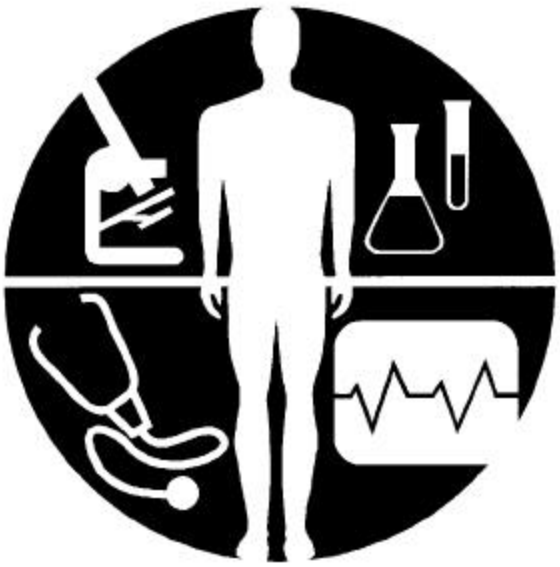
APPENDIX J

DOE BROCHURE
PROTECTING WORKERS WHO ARE HUMAN RESEARCH SUBJECTS

Protecting Human Research Subjects

within the Department of Energy

ARE YOU CONDUCTING RESEARCH USING HUMAN SUBJECTS?



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The following information is contained in the "Protecting Human Subjects," shown on page A-69.

Protecting Workers Who Are Human Research Subjects

Workers Who Participate in Research are Entitled to Protection

The Department of Energy (DOE) has a long-standing commitment to protect the health of workers at its sites. As a DOE employee or DOE contractor employee, you make important contributions to site cleanup, national security, scientific advancement, and other major goals. DOE recognizes the obligation to protect your health and safety--not only when you do your routine work, but also when you are asked to participate in research.

Employees at DOE sites are sometimes asked to be participants in research projects, which include worker health studies. If you are asked to be a participant, you should know the requirements for protecting your rights to information, privacy, and well-being. These requirements apply to all kinds of research, including studies where:

- Researchers use private information that can be readily identified with individuals, even if the data was not collected specifically for the study.
- Researchers seek "generalizable knowledge" about categories of people, such as DOE workers. One example is health studies that look for links between job conditions or hazards and adverse health effects.
- Researchers test new devices, products, or materials using volunteers.
- Researchers collect data by "intervention or interaction" with individuals. Intervention includes not only physical procedures (like drawing blood), but also manipulation of a subject's environment.
- Researchers use bodily materials such as cells, blood, and urine, hair that may or may not have been collected specifically for the study.

The "Common Rule" Defines Protection of Human Subjects

The obligations to protect human subjects apply to research conducted using DOE facilities or property, supported with DOE funds, or performed by DOE employees or contractors. The requirements are found in the Common Rule, *Federal Policy for the Protection of Human Subjects* (Title 10, Code of Federal Regulations, Part 745).

The Common Rule States:

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

A *human subject* is “a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with individual, or (2) identifiable private information.”

The DOE Office of Energy Research is responsible for making final decisions as to what constitutes DOE-related human subject research and how human subject protection must be implemented. (Secretary of Energy Federico Pena, Memorandum to All DOE Employees, Update on Department Policy for the Protection of Human Subjects in Research, January 20, 1998.)

Study INFORMATION Must Be Given in Everyday Language.

The key to protecting research subjects is “informed consent.” Informed consent is person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research. Doctors also must seek informed consent before a patient undergoes a medical procedure.

Potential research subjects can give informed consent only if they have all the information about the study they need to decide whether to participate. Informed consent respects each individual's right to make choices.

If you are asked to participate in a study of workers' health or other research, expect to get information in your first contact with the researcher. That information must be in everyday language a non-specialist can understand.

Ideally, the research should give you a fact sheet, brochure, or even a videotape to review. The material should answer these questions:

1. What is the purpose of this research?
2. What benefits are expected for me as an individual participant, or for society?
3. Who is sponsoring and conducting the research?
4. How long will I be expected to participate?
5. How and why was I chosen for the study?
6. What tests or procedures will the study involve: Do they have risks? Will they cause pain or discomfort (physical or mental)?
7. Who can use or obtain study data and results, including any personal records about me?
8. Who do I contact for questions and information?
9. How will the results be published or reported?
10. How will my privacy be protected when the research is reported?
11. Where do I get help if I think I am being pressured to participate in a study or if I think I am not being treated appropriately?
12. How do I withdraw from a study if I change my mind later?

13. Are there appropriate alternative procedures or courses of treatment?

Every worker subject should expect to be able to obtain information on all studies that request data from him or her or that use the worker's records.

PRIVACY Is a Human Right Researchers Must Respect.

You are entitled to assurances that your privacy will be protected in the study. The researcher should be able to explain the steps being taken to keep participants' identities confidential. Your individual identity should not be revealed in study activities or in published reports of the research.

Another privacy issue concerns how much you will be told about the results. Some people may agree to be research subjects because they want to know the findings, particularly anything specific about themselves. Others like just knowing that removal of identifiers to protect privacy or other features of the research plan may limit the information you can receive about your own results.

The important message is: Know the exact terms of the study *before* you consent to participate.

PROTECTION of the Participants' Well-Being is a Key Researcher Responsibility.

Since ancient times, a doctor's first commitment to patients is “to do no harm.” The same principle applies to research--medical and other types--with human subjects.

Protecting research subjects from physical harm seems like an obvious requirement. But studies with human subjects must also include protections from psychological, social, or economic harm. For example, information about you obtained in research may not be used to disqualify you from work, limit your access to medical or life insurance, or limit your access to other business or community services that would otherwise be available to you.

Human Subject Rights and Researcher Responsibilities are Mirror Images of One Another

If you are asked to be a subject in a research study, know your RIGHTS to...	If you conduct research that includes human subjects, know your RESPONSIBILITIES to...
Receive complete information on the study so that, if you freely agree to participate, you can give informed consent.	Provide research subjects with complete information--in simple, understandable terms--about your research so that they can give informed consent.
Expect protection of your physical, psychological, and economic well-being.	Protect their physical, psychological, and economic well-being.
Receive fair, impartial treatment by the researchers.	Be fair and impartial in selecting and dealing with research subjects.
Receive respect for your privacy and	Respect the rights of research subjects and

assurance that information about you will be kept confidential.	protect the confidentiality of information about them.

If you are a worker who is asked to participate in a study, take an active role by asking the researcher how the study has been designed to protect you. Remember, too, that you always retain the right to withdraw from the study.
If you are a researcher designing a study, incorporate protections from the beginning of the project. Be prepared to answer questions and to talk with participants throughout the study about experiences that concern them or fears they may have about the effects of tests, the handling of records, and the protection of confidentiality.

The Role of the Institutional Review Board in Protecting Human Subjects

All human subjects research conducted by or in DOE facilities must be reviewed by an Institutional Review Board (IRB). The IRB is an independent group of scientists and community representatives from the area where the research group is located.

The IRB must review and approve research involving human subjects *before* the work begins. If the research continues, the IRB must review and approve the project at least once a year. If the procedures with human subjects change, the IRB must review and approve these changes.

This process is designed to ensure that the study protects the rights and welfare of human subjects--for example, by minimizing risks, selecting subjects equitably, obtaining informed consent, and ensuring privacy and confidentiality.

The IRB must be notified immediately if a human subject is injured, if private information is disclosed improperly, or if other events occur that could have harmful consequences for the participants.

Who Will Answer My Questions?

If you have questions or concerns about human subject protection, contact:

The researchers,
The IRB,
Your local Human Subjects Coordinator, or
The DOE operations office point of contact for the study.

These individuals can provide you with site policies and other material on protecting human research subjects. You can also find additional information in other publications of DOE's Human Research Subject Program:

DOE Human Subjects Research Handbook, 2nd ed.
Protecting Human Research Subjects newsletter, 1992-1998
Protecting Human Subjects Brochure/Poster

If copies are not available locally, request them from:

Human Subjects Program
Office of Science, SC-72
U.S. Department of Energy
19901 Germantown Road
Germantown, MD 20874-1290