



## Fact Sheet

### Background

The protection of human research subjects is of primary importance to the Department of Energy (DOE). All research involving human subjects conducted for, by, or at DOE institutions, including classified and proprietary research, domestic or international, must fully comply with all applicable federal regulations and DOE requirements.

The DOE Human Subjects policy was established in 1991 under 10 CFR 745, the DOE version of the Common Rule. Requirements for implementing this policy are described in DOE Order 443.1B, Protection of Human Research Subjects, which ensures that DOE keeps pace with the changing and complex nature of human subject research, develops and implements comprehensive educational programs, and performs program compliance reviews.

The DOE Human Subjects Protection Program (HSPP) is located in the Office of Biological and Environmental Research (OBER), which is part of the Office of Science. OBER oversees the program in collaboration with the National Nuclear Security Administration (NNSA), which has responsibility for research involving defense elements within DOE (Lawrence Livermore National Laboratory, Los Alamos National Laboratory, and Sandia National Laboratories).

Protecting human subjects is a team effort, with DOE federal employees, DOE laboratory/contractor employees, and research funding recipients outside the DOE system, all sharing equally in the responsibility. All DOE human subject research is reviewed and approved by a registered IRB operating under a valid Federal Wide Assurance (FWA) throughout the life of the study.

DOE sites are as unique as they are geographically dispersed. They conduct a wide variety of human subjects research for both the government and the private sector. Over 1 million human subjects currently participate in DOE-funded or conducted research. Of approximately 600 ongoing projects, approximately 50 percent have been determined to meet the Common Rule exempt criteria. The remaining projects, which are reviewed under expedited or full board procedures, span three general categories of research including clinical, socio-behavioral, and biomedical/other. Some examples include ergonomic research, development of antibody profiling tests, innovative imaging techniques to explore physiology and chemistry of the brain, and tackling particularly challenging dilemmas called "wicked problems."

### U.S. Department of Energy Outreach

The U.S. Department of Energy (DOE) Human Subjects Protection Program fosters communication among all engaged in or affected by DOE research -- Institutional Review Board (IRB) members and administrators, researchers and their management, institutional officials, sponsors, and potential human subjects. DOE recognizes that it is equally important to reach out beyond its research community to the global human subjects protection family. DOE-developed resources are used to share information and help continually improve processes and practices for ensuring the ethical conduct of research.

## DOE's Human Subjects Research Database

DOE maintains, in a publicly available database, information on non-exempt research projects funded by DOE, conducted in DOE facilities, performed by DOE personnel, or involving information on DOE or DOE contractor personnel. Project information is obtained annually from a questionnaire completed on-line by principal investigators conducting work for DOE. Data are available from 1995 through 2011. The database was an invaluable tool in responding to an urgent request from the Presidential Bioethics Commission for more detailed information on DOE human subjects research projects. The Oak Ridge Institute for Science and Education (ORISE) maintains this database for DOE, which can be found at: <http://www.ornl.gov/hsrdreport/>.

## Community IRB Members

The voice of the community thru the community IRB members is essential to protecting human subjects. DOE helps community members become successful IRB participants by providing them access to resources, training, hands-on experience, one-on-one mentoring, and networking with other community members. For example, community members from DOE IRBs attend PRIM&R-sponsored Advancing Ethical Research conferences. DOE also sponsors joint workshops with academic and medical institutions' community members. In December 2010, DOE and the University of Southern California (USC) held a joint workshop focused on enhancing the voice and role of the community member in the IRB process. Organizers and participants agreed to follow up on a number of strategies generated during the discussion. Among those strategies were a commitment by DOE and USC to hold biannual educational teleconferences for community IRB members nationwide (the first of which was held in June 2011) and a commitment by DOE to revitalize its listserv. DOE also contributed to PRIM&R's July 2011 webinar, "Community IRB Members: Supporting their Involvement to Advance Research."

## Central IRB Partners with Site-Specific IRBs

DOE has both a Central IRB (CDOEIRB) and site-specific IRBs. Nine of 12 DOE national laboratories/facilities conducting human subjects research have their own internal IRB. The other three use an external IRB to review items not under the purview of the Central IRB. The CDOEIRB includes representatives from the site IRBs, as well as external members. DOE considers the focus, strengths, and resources of each to help determine whether a local or central perspective is a better fit for addressing changing needs and emerging issues in the protection of human subjects. New areas of involvement for the CDOEIRB are of potential use to manage classified projects and to address sensitive programs from other agencies such as the Department of Defense.

## Human Subjects Working Group

In 1988, a group of IRB administrators and chairpersons attended the first meeting of DOE's Human Subjects Working Group (HSWG). This meeting proved to be the beginning of what would become a strongly influential group composed of DOE field and headquarters officials, IRB chairs, administrators, and members, program and project managers, other government agency officials (National Institutes of Health, National Institute for Occupational Safety and Health), university and hospital staff, various experts, and former DOE workers. The HSWG was created to provide educational and networking opportunities for the DOE human subjects community, and has evolved into a dynamic, PRIM&R-like resource that meets in person twice a year, has monthly conference calls, and communicates electronically on a regular basis. The HSWG is a living realization of DOE's commitment to the protection of human research subjects.

## For More Information

DOE Human Subjects Protection Program Manager U.S. Department of Energy Office of Science (SC) 301-903-7693 <a href="mailto:Elizabeth.White@science.doe.gov">Elizabeth.White@science.doe.gov</a>	NNSA Human Subjects Protection Program Manager U.S. Department of Energy National Nuclear Security Administration (NA) 201-586-0142 <a href="mailto:John.Ordaz@nnsa.doe.gov">John.Ordaz@nnsa.doe.gov</a>	Human Subjects Program Technical Support Oak Ridge Institute for Science & Education 865-576-3316 <a href="mailto:Denise.Viator@orise.ornl.gov">Denise.Viator@orise.ornl.gov</a>
---	--	---

## Resources

### **DOE Human Subjects Protection Program Website**

The purpose of this website is to enhance communications among Institutional Review Board members and administrators, researchers, institutional officials, management, and potential human subjects within the DOE research community. It also serves as a vehicle to reach out to other individuals and organizations in the global human subject protection family.

<http://humansubjects.energy.gov/default.htm>

### **DOE Protection Human Research Subjects Newsletter**

The newsletter addresses current human subjects research issues and concerns that are of interest to the DOE community and often to the broader human subjects protection community as well. <http://humansubjects.energy.gov/doe-resources/newsletter/default.htm>

### **DOE Human Subjects Research Database (HSRD)**

The DOE HSRD contains information relating to research projects involving human subjects (projects reviewed by an IRB and not given "exempt" status) that are currently funded by the DOE, or are performed at DOE facilities with support from other sponsors, or performed by DOE personnel or DOE contractor personnel. This database includes a searchable interface, detailed descriptions of each research project and a section that summarizes the information for quick referencing. Currently the database is administered by ORISE.

<http://hsrd.ora.gov/>

### **DOE Human Subjects Protection Resource Book**

This book (though outdated) synthesizes available information on the protection of human subjects in research and the application of such information. DOE, over the next year, hopes to partner with other interested organizations to update this Resource Book.

<http://humansubjects.energy.gov/doe-resources/humsubj-resourcebook.htm>

### **From Paper to People: After IRB Approval of Research Studies**

This guide provides an overview of both novel and routine ways to assist Institutional Review Boards (IRB) in ensuring that human subject studies, once approved, are conducted properly and follow accepted ethical principles. It is intended as a supplement to human subject protection requirements and not in lieu of the regulations.

<http://humansubjects.energy.gov/doe-resources/files/P2Pbook.pdf>

### **DOE Human Subjects Information Brochure**

This brochure introduces researchers, research subjects, laboratory officials, and others involved in human subject research to regulations and policies established to protect human subjects participating in research.

<http://humansubjects.energy.gov/doe-resources/researcher-brochure.htm>

### **Worker Studies Informational Brochure**

This brochure addresses the rights and concerns of DOE workers who participate as human research subjects.

<http://humansubjects.energy.gov/doe-resources/worker-brochure.htm>