

## *Human Subjects Research Database*

The HSRD is compiled annually to ensure that the database is current, both to add new information and to update existing information. In addition to this database, other DOE information tools regarding human subject activities are available through the web sites for the DOE and Office of Biological and Environmental Research within the Office of Science.

The database may be accessed through the following Web sites:

DOE Protecting Human Subjects home page:  
<http://humansubjects.energy.gov>

ORISE home page:  
<http://orise.orau.gov>



OAK RIDGE INSTITUTE FOR SCIENCE AND EDUCATION

Comments, questions, or suggestions for improvement of this database are welcome and may be directed to:

Donald R. Watkins, Ph.D.  
Human Subjects Research Database  
Project Manager  
Oak Ridge Institute for Science and Education  
ORAU/Mail Stop 50  
P.O. Box 117  
Oak Ridge, TN 37831-0117  
Phone: 865-241-3744  
Fax: 865-576-7903  
E-mail: [Don.Watkins@orise.orau.gov](mailto:Don.Watkins@orise.orau.gov)

Questions on the DOE Human Subjects Research Program may be directed to:

Human Subjects Research Program  
U.S. Department of Energy  
Office of Biological and Environmental  
Research  
SC-23.2, Germantown Building  
19901 Germantown Road  
Germantown, MD 20874-1290  
Phone: 301-903-3213  
Fax: 301-903-0567  
E-mail: [humansubjects@science.doe.gov](mailto:humansubjects@science.doe.gov)



Office of  
Science

U.S. DEPARTMENT OF ENERGY

## *Human Subjects Research Database*

## ***Human Subjects Research Database***

*The Human Subjects Research Database (HSRD), mandated by Department of Energy (DOE) Orders 443.1 and 481.1 under DOE Policy for Protection of Human Subjects (10 CFR Part 745), is updated yearly and maintained by the Oak Ridge Institute for Science and Education (ORISE) in Oak Ridge, TN. It contains information on all research projects involving human subjects that are not exempt by their local Institutional Review Board (IRB) and are funded by the DOE, conducted in DOE facilities, performed by DOE or contractor personnel, or use DOE workers as human subjects. Some additional health studies that relate to DOE activities may also be included in the database.*

*The database consists of a detailed description of each research project and a summary section for quick referencing. Statistical information to track growth areas is compiled annually from the database. Project information is obtained from a questionnaire*



## ***Human Subjects Research Database***

*completed on-line by the principal investigator. Any questions relating to individual projects should be directed to the listed public information contact.*

*By definition, “research involving human subjects” can include a variety of activities ranging from actually acquiring samples or specimens from human volunteers to gathering information using questionnaires or using existing information such as medical records. Some projects involving human subjects are therapeutic in nature; some include efforts to develop new instrumentation or techniques; some involve the use of trace quantities of radioactive material in imaging studies; others involve only the analysis of body fluid samples; and still others involve follow-up studies on workers previously employed at sites that stored or used radioactive materials. Many research projects are epidemiological in nature and involve only the analysis of medical records of subjects to identify patterns of illness.*



## ***Human Subjects Research Database***

*All research involving human subjects that is funded by DOE (or any other Federal agency) and/or carried out at DOE facilities must be approved by an IRB located at the DOE site (or, if the site has no IRB, the IRB designated by that site and approved by the DOE Human Subjects Research Program Manager). This local IRB is the cornerstone of the system of protection of human subjects. No human subjects research may be initiated and no ongoing research may continue in the absence of IRB approval. The IRB is charged with meeting bioethical standards and ensuring that all approved projects are in compliance with the Federal Policy on Protection of Human Subjects (45 CFR Part 46). This policy was drafted with DOE assistance in the 1980s and was adopted by DOE (10 CFR Part 745) and 16 other Federal agencies (including the Department of Health and Human Services) in July 1991. The policy provides uniform guidelines for all who are involved in Federally sponsored research. Responsibility for the protection of human subjects at the DOE resides in the Office of Science.*

