



PNNL Institutional Review Board Human Subjects Research Program

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Introduction

It is both a privilege and a serious responsibility when an investigator uses another human as a subject of research, be it actual physical interaction with that person or use of their biological tissues, genetic or private information.

The federal government has developed a set of laws known as the "Common Rule" which are promulgated from ethical standards set forth in the [Belmont Report](#), [Nuremberg Code](#) ([PDF](#)), and [Declaration of Helsinki](#) to guide researchers in the conduct of this work and to protect the rights and welfare of human subjects.

The Common Rule was adopted in 1991 by sixteen federal agencies that support, conduct or otherwise regulate human subjects research. For the U.S. Department of Health and Human Services (DHHS), the Common Rule is implemented at [45 CFR 46, Subpart A](#). For the Department of Energy (DOE), the Common Rule is implemented at [10 CFR 745](#) ([PDF](#)). Battelle Corporate Policy for human subjects research may be found in the [Regulations, Standards, Policies, and Other Sites of Interest](#) section of this web site.

PNNL conducts a broad and diverse range of activities that involve human subjects. Researchers analyze breath for toxic substances, develop telemedicine diagnostic systems and analyze children's fingerprints. They also conduct software usability evaluations, study human cells on a molecular level and gather cultural oral histories.

Rapidly advancing technologies and increasing threats to personal privacy present serious challenges to the investigators responsible for protecting the rights and welfare of the subjects who make this research possible.

To meet its responsibility for safeguarding the rights and welfare of human



Ultrasound Teleradiology/Telepresence Diagnostic System

subjects involved in research, the Pacific Northwest National Laboratory (PNNL) maintains a committee known as the **Institutional Review Board** (IRB). The IRB is responsible for reviewing a wide variety of activities that involve humans as subjects in research.

Research Activities that Require Review by the IRB Include:

- Human beings as subjects to test devices, products or materials developed through research.
- Private information that can be readily identified with individual persons or their families, even if the information was not collected for this study, such as employment, radiation exposure, medical, or legal records.
- Studies conducted to gain knowledge that can be generalized about categories or classes of human beings, such as oral history projects, DOE workers, or culturally diverse populations.
- Human beings to evaluate environmental or ergonomic alterations such as the effects of lighting options on productivity.
- Data collected through intervention or interaction with human beings such as drawing blood, breath analysis, or X-rays; interviews or web-based surveys, video or audio taping for the purpose of research and generalizable scientific knowledge.
- Biological materials derived from humans; organs, tissues, biofluids (i.e., urine, blood, blood products) or specimens (i.e., skin, hair, teeth,); cells or cell lines (i.e., primary or established cell cultures); sub-cellular (i.e., organelles) or molecular (i.e., DNA, RNA, protein) constituents.

This web site is designed to familiarize you with the PNNL Human Subjects Program. The **Roles and Responsibilities** section describes the basic responsibilities of management, the IRB, and research staff. The **Human Subjects** site in the PNNL Standards Based Management System (SBMS) provides the policies, procedures and tools needed to properly conduct human subjects research from proposal development to program completion.

NOTE: Human subjects research may not begin or continue without (1) IRB approval and (2) documentation that key research staff have completed human subjects training.

If you have questions or need additional information, contact **Sherry Davis**, IRB Program Manager. Comments or suggestions for this web site are welcome.

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Pagemaster: [Carol Elledge](#)

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