



## PNNL Institutional Review Board Human Subjects Research Program

### Regulations, Orders, Policy Statements and Other Sites of Interest

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Assurances:  
FWA4696 - IRB0285  
HHS MPA-1221  
DOE.MPA.PNNL-2005

#### *DOE*

- [DOE Protecting Human Subjects Home Page](#)
- [Human Genome Project \(HGP\)](#)
- [Human Subjects Policy Statement](#)
- [Human Subjects Research Database \(HSRD\)](#)
- [10 CFR Part 745 - Protection of Human Subjects](#) [PDF](#)
- [Order 443.1 - Protection of Human Subjects](#) [PDF](#)
- [Policy 443.1 - Protection of Human Subjects](#) [PDF](#)
- [Order 481.1B - Work for Others \(Non-Department of Energy Funded Work\)](#) [PDF](#)
- [DOE Openness: Human Radiation Experiments](#)

#### *DHHS/NIH*

- [NIH Division of Extramural Research, Ethical, Legal, and Social Implications \(ELSI\) Research Program](#)
- [NIH Office of Human Subjects Research \(OHSR\)](#)
- [DHHS Office for Human Research Protections \(OHRP\)](#)
- [45 CFR Part 46 - Protection of Human Subjects](#)
  - [Subpart A - Federal Policy for the Protection of Human Subjects \(Basic DHHS Policy for Protection of Human Research Subjects\)](#)
  - [Subpart B - Additional DHHS Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization](#)
  - [Subpart C - Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects](#)
  - [Subpart D - Additional DHHS Protections for Children Involved as Subjects in Research](#)
- [NIH Human Genome Project](#)
- [NIH Bioethics Resources on the Web](#)
- [NIH How to Write a Human Subjects Grant Application](#)

#### *FDA*

- [CFR Title 21, Part 361.1 - Radioactive Drugs for Certain Research Uses](#)
- [CFR Title 21, Part 50 - Food and Drug Administration \(FDA\) Human Subjects Regulations](#)
- [Information for Health Professionals](#)
  - [Clinical Trials and Human Subject Protection](#)
- [Center for Biologics Evaluation and Research \(CBER\)](#)
- [Licensed Establishments and Products](#)

- CDC**
  - [Confidentiality Booklet](#) **PDF**
- Washington State**
  - [HRRB - Laws and Regulations](#)
- Battelle**
  - [DOE/PNNL Multiple Project Assurance](#)
  - [Corporate Policies 1.1.1.6 & 1.1.1.7](#) **PDF**
- Other**
  - [National Bioethics Advisory Commission \(NBAC\)](#)
  - [Public Responsibility in Medicine and Research \(PRIM&R\)](#)
  - [Advisory Committee on Human Radiation Experiments \(ACHRE\) \(at the National Security Archive\)](#)
  - [Applied Research Ethics National Association \(ARENA\)](#)
  - [Code of Federal Regulations \(CFR\)](#)
  - [Oral History Association](#)

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