

U.S. Department of Energy
Human Subjects Protection Program
**ANNUAL REPORT
FISCAL YEAR 2015**



Protecting Human Subjects in Research



Photo Credit: Eddie Bright, Geographic Information Science & Technology, Oak Ridge National Laboratory.

Legend:

This 3-D visualization represents projected changes in U.S. population between 2010 and 2050 as projected by LandCast. Areas seen in red indicate higher levels of population growth, whereas the vertical spikes signify population growth with new land development

Foreword

In 1991, 16 U.S. Federal agencies, including the Department of Energy (DOE), signed on to a set of regulations designed to guide and govern the conduct of research activities involving human subjects, better known as the Common Rule. These regulations arose from several prior standards: the Nuremberg Code, written in the 1940s in response to Nazi medical research atrocities; the 1964 Declaration of Helsinki developed by the World Medical Association; and the basic ethical principles of the 1979 Belmont Report, with which the Common Rule is most closely associated and which are more clearly described in this report.

The protection of human subjects is paramount in all research activities supported or performed by DOE. All research conducted at DOE institutions, supported with DOE funds, or performed by DOE employees, including that which is classified and proprietary, and conducted domestically or in an international environment must comply with all applicable Federal regulations and DOE requirements for the protection of human subjects.

We take great pride in the DOE Human Subjects Protection Program and offer this report to give you a broader overview of the program, its management, mission, and strategic goals.



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Executive Summary

The [U.S. Department of Energy \(DOE\) Human Subjects Protection Program \(HSPP\)](#) is pleased to present this year's annual report. The DOE HSPP was mandated as part of 45 CFR 46, promulgated for DOE under 10 CFR 745 in Fiscal Year 1993. This report presents an overview of the DOE HSPP's structure, accomplishments, and future endeavors.

In 1991, Secretarial delegation gave the Office of Science (SC), Office of Biological and Environmental Research, the responsibility for ensuring protection of human subjects in all research funded under DOE authorities. The DOE Order gives the Under Secretary for Science overarching responsibilities, with the National Nuclear Security Administration (NNSA) having separate (and in many cases parallel) responsibilities with regard to DOE's NNSA sites that conduct human subjects research. Despite this, SC and NNSA made a policy decision to combine as one the programs for human subjects protection for all DOE/NNSA sites. The DOE and NNSA Human Subjects Protection (HSP) Program Managers engage the Office of Intelligence and Counterintelligence on intelligence-related human subject issues. They also work closely with the Office of Health and Safety (AU-10), which funds a number of human subjects research studies and co-funds (with SC and NNSA) the Central DOE Institutional Review Board (IRB).

The central tenets of the DOE/NNSA HSPP include:

- DOE adoption of the Common Rule (Subpart A) through 10 CFR 745.
- DOE-specific requirements (DOE Order 443.1B, Protection of Human Research Subjects, which also includes adoption of 45 CFR 46, Subparts B through D).
- A Central DOE IRB for sites without an IRB, beryllium-exposure related health studies involving DOE workers, multi-site protocols, the Former Worker Medical Screening Program, and a portion of other DOE-funded research at outside insitutions.
- A Central DOE IRB-Classified for sites with classified projects that do not have a classified IRB, multi-site classified protocols, and a portion of the research overseen by DOE's Office of Intelligence and Counterintelligence.
- Guidance documents for use by DOE sites in implementing Federal and DOE-specific requirements.
- A publicly accessible Human Subjects Research Database to track DOE-funded and DOE-conducted research.
- A website with various resources for the public, IRB members, and researchers, including FAQs.

- Corporate DOE funding of Collaborative Institutional Training Initiative (CITI) and other educational resources, such as DOE site and central DOE IRB representation at the annual training meeting of Public Responsibility in Medicine and Research (PRIM&R), a professional organization that advances ethical standards in research.
- Proactive DOE Human Subjects Working Group, representing DOE Headquarters organizations and 17 DOE sites that conduct human research, with regular conference calls and an annual in-person meeting to share lessons learned, best practices, and expert presentations on topics of high interest (e.g., protection of personally identifiable information, data security, internet research).
- Strong partnership with DOE program offices and the Office of General Counsel.
- DOE site/laboratory IRB evaluations on a 3- to 4-year cycle, modeled after the Department of Health and Human Services Office for Human Research Protections (OHRP) quality assurance consultations.
- External independent review of the DOE Headquarters program every 3 to 4 years.
- Representation on interagency human subjects protection working groups.

1.0 Program Overview

Mission/Strategic Goals

The purpose of the U.S. Department of Energy (DOE) Human Subjects Protection Program (HSPP) is to assure that the risks to human subjects involved in research performed by or for DOE are minimized and reasonable in relation to the anticipated benefits that may accrue to them or to society as a whole and to protect the rights and welfare of those subjects in accordance with Federal regulations, state laws, DOE directives, international laws (as applicable), and ethical principles.

Governing Principles

The DOE HSPP is guided by the ethical principles set forth in the Nuremberg Code, Belmont Report, and the Declaration of Helsinki, including the following three principles as outlined in the Belmont Report:

- **Respect for Persons:** requires that potential subjects be given the information they need, in language they understand, to decide whether or not to participate in a study, as well as the time and opportunity necessary to make that decision without any pressure to participate. It further requires protection of subject privacy, confidentiality of data, and increased protection for vulnerable populations.
- **Beneficence:** requires that researchers (and their institutional organizations) minimize the probable risk(s) and maximize the potential benefit(s) to the subjects and/or society in which they participate.
- **Justice:** requires that the benefits and burdens of research be distributed fairly. Subjects should be recruited on the basis of their relation to the problem under study rather than their easy availability, their compromised position, or their malleability. Investigators should base inclusion/exclusion criteria on those factors that most effectively and soundly address the research problem. For example, subjects should not be denied access to a study simply because they may not speak English.

DOE Human Subjects Research Portfolio

At DOE, the determination of what constitutes human subjects research is made jointly by the Office of Science (SC) and National Nuclear Security Administration (NNSA).

DOE's research using human subjects encompasses a broad range of topics. In addition to traditional biomedical and clinical studies, DOE-funded/conducted human subjects research includes, but is not limited to, studies that:

- Involve humans to test devices, products, or materials developed through research, to examine human-machine interface, or to evaluate environmental alterations.

- Use personally identifiable bodily materials such as cells, blood, tissues, urine, or hair, even if the materials were collected previously for a purpose other than the current research.
- Collect and use private information that is readily identifiable, including genetic information and medical and exposure records, even if the information was collected previously for a purpose other than the current research.
- Collect personally identifiable or non-identifiable data through direct intervention or interaction with individuals.
- Search for generalizable knowledge about categories or classes of subjects, such as worker populations or subgroups (e.g., linking job conditions of worker populations to hazardous health outcomes).

2.0 Program Organization

DOE and NNSA Human Subjects Protection (HSP) program managers are responsible for working closely with all DOE Headquarters organizations that fund human research and with the 17 DOE sites that conduct human subjects research to:

- Ensure compliance of DOE-funded and DOE-conducted human subjects research with Federal and DOE-specific requirements.
- Keep DOE sites apprised of national and international human subjects regulatory issues.
- Develop and implement DOE requirements and guidance.
- Assist DOE sites with challenging new issues.
- Provide education, training, guidance, and tools for DOE's site and Central Institutional Review Boards (IRBs) and their researchers.
- Oversee the Central DOE IRB and the Central DOE IRB-Classified (C).
- Maintain an open dialogue with all members of the DOE complex to establish and communicate DOE objectives and needs to site offices, site IRBs, and the central DOE IRBs.
- Support community involvement/membership on IRBs.

DOE/NNSA HSP program managers also work closely with the Office of Intelligence and Counterintelligence (IN-1), and the Office of Environment, Health, Safety and Security's Office of Health and Safety (AU-10) in the management of the central DOE IRBs and in oversight of research that falls under the purview of those two offices.

The strength of the DOE HSPP lies in its focus on communication and coordination among all levels of management, the DOE Headquarters central IRBs, and the Human Subjects Working Group, which is comprised of knowledgeable, on-the-ground representatives, usually the IRB Chair and Manager/Administrator, from each of the DOE sites that conduct human subjects research. In addition to the DOE Institutional Official (IO), who oversees the entire DOE program for the protection of human research subjects, each DOE site conducting such research has its own IO, a designated IRB, and an IRB manager responsible for the day-to-day operation of the site's program.

Central DOE IRBs

As mentioned on the previous page, in addition to the [DOE laboratory/site-specific IRBs](#), DOE has two central IRBs: the Central DOE IRB and the Central DOE IRB-C.

The Central DOE IRB was established in January 2010 by four DOE Headquarters organizations: the SC, HSS (now AU), NNSA, and IN.

This IRB evolved from DOE's Central Beryllium IRB, which was established in 2001 to bring vision, expertise, and consistency to the review of all DOE-funded/conducted human subjects research and screening related to occupational exposure to beryllium. In 2010, the scope of this IRB was expanded and the name was changed to the Central DOE IRB. This IRB serves as DOE's IRB of record for study protocols that involve employees of DOE or its contractors and/or are explicitly funded by, or conducted by, DOE or other agencies or institutions in the following areas:

- Beryllium exposure-related studies.
- The Former Worker Medical Screening Program (FWP).
- Multi-site/laboratory research within the DOE complex.
- A portion of DOE's energy efficiency-related human subjects research.

In addition to providing reviews for multi-site programs, the Central DOE IRB provides reviews for DOE sites that do not have an IRB or that do not have IRB members with the necessary expertise. The Central DOE IRB-C will also provide such reviews, as well as reviews for sites that have IRBs but do not have members with the proper security clearances needed to review classified human subjects research. These boards also provide IRB review for outside organizations that are conducting DOE-funded research but do not have institutional IRBs.

The Central DOE IRB-C reviews only protocols that are classified or protocols that are sensitive because of the nature of the work—primarily intelligence-related studies—and may likely become classified.

DOE 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 initial gathering proved to be the beginning of what would become a large active group composed of DOE Field and Headquarters officials, IRB members, program and project managers, other government agency officials (National Institutes of Health, National Institute for Occupational Safety and Health [NIOSH]), researchers, various subject matter experts, and former DOE workers. The HSWG provides educational and networking opportunities and promotes ongoing dialogue and discourse between the DOE HSPP and individual site programs. Members of the HSWG share experiences and support each other in a broad sense in solving problems on a daily basis. Establishing the HSWG formalized DOE's commitment to protecting human subjects in research studies. The DOE and NNSA human subjects protection program managers co-chair the HSWG.

DOE Sites Conducting Human Subjects Research and Key Research Programs Funded by DOE Headquarters Program Offices

Human subjects research is funded by and/or conducted at multiple DOE sites (see Figure 1 below) and several DOE program offices. Nine of the DOE sites engaged in human subjects research use an internal IRB. Other sites use external IRBs and/or the Central DOE IRBs. Collectively, these research projects are performed with annual funding over \$122M in combined DOE and outside funding.

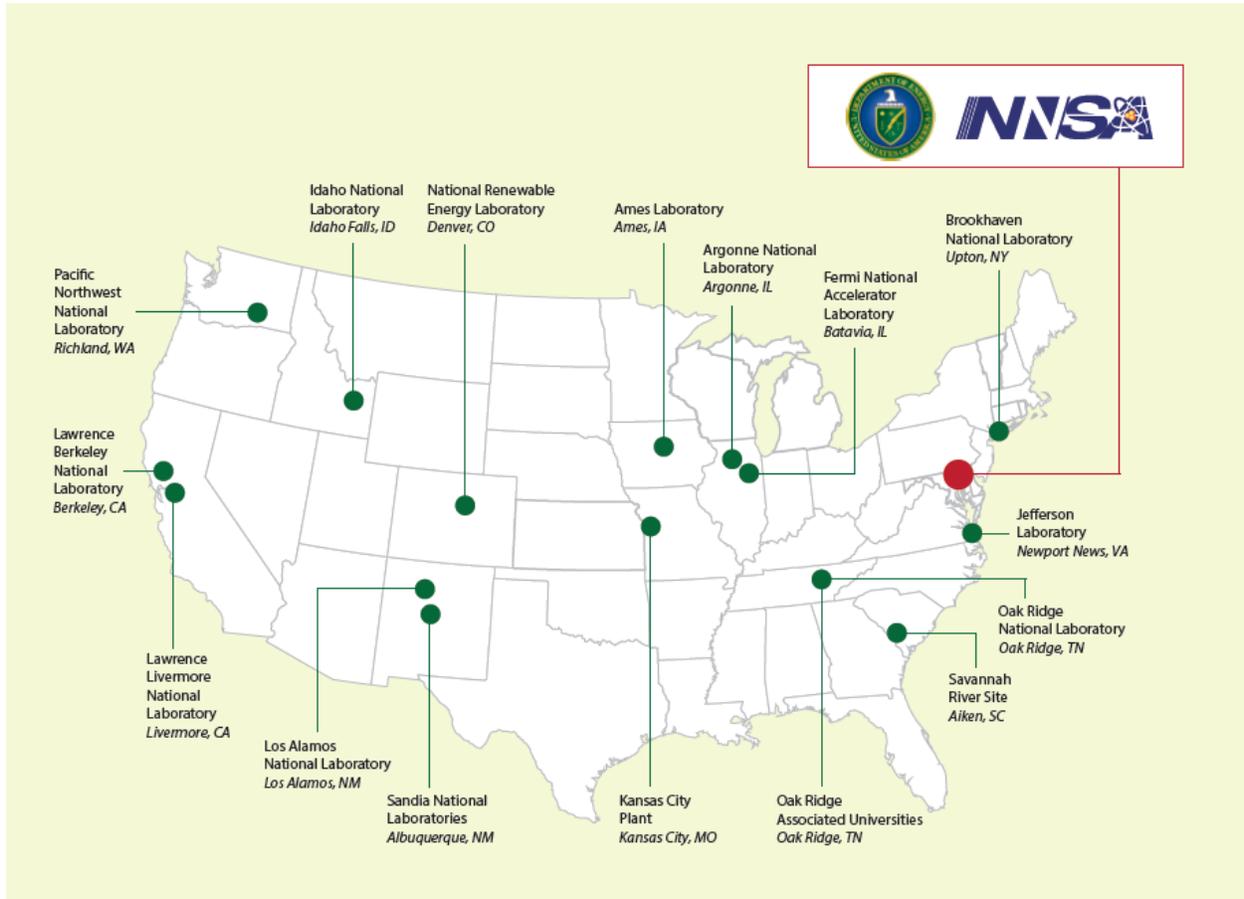


Figure 1: DOE Locations Funding and/or Conducting Human Subjects Research

3.0 Program Implementation

Role of DOE's Institutional Review Boards

DOE central and site IRBs are responsible for identifying human subjects research activities and then conducting in-depth ethical and technical reviews of the protocols brought before them. Their job is to ensure that risks to subjects are minimized and reasonable in relation to any anticipated benefits to the subjects themselves or to society as a whole. IRBs must determine that the involvement of subjects is equitable, their privacy is protected, informed consent is obtained, and data are protected. IRBs must ensure that subjects are treated with respect and are fully protected under the law. To fulfill these requirements, government regulations require that the membership of the IRBs meet all of the following criteria:

- Be comprised of at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
- Be sufficiently qualified through the experience, expertise, and diversity of its members, with sensitivity to local community issues and attitudes.
- Possess professional competence to review research activities and be able to ascertain the acceptability of proposed research in terms of their institution's commitments and regulations, applicable law, standards of professional conduct, and practice.
- Include individuals knowledgeable about and experienced in working with vulnerable subjects such as prisoners, children, pregnant women, or handicapped or mentally disabled persons when those populations are used as subjects.
- Not be comprised entirely of men or entirely of women nor consist entirely of members of one profession.
- Include at least one member whose primary concerns are in scientific areas and at least one whose primary concerns are in non-scientific areas.
- Include at least one member who is not affiliated with the institution in any manner.
- Invite subject matter experts to assist in reviews as needed.

Importance of Active Community/Unaffiliated Members on Each of the DOE IRBs

DOE values the input of the community or unaffiliated members on its IRBs. Community members see the research with a fresh eye and may identify issues that institutional IRB members do not see. For many years, DOE has had a listserv aimed at providing educational information for and linking community IRB members nationwide. Additionally, in recent years, with the goal of enriching the experience of serving as a community IRB member by enhancing the voice of community IRB members nationwide, DOE and the University of Southern California (USC) have jointly hosted periodic educational webinars on human subjects research topics of interest.

DOE Human Subjects Research Database

The DOE [Human Subjects Research Database \(HSRD\)](#) is a publicly available database detailing human subjects research projects funded or conducted by DOE or its sites or that use DOE workers as subjects. The database was created initially in the early 1990s as a management tool to increase transparency regarding DOE research. It is updated regularly. Over the years, it has served as a resource for the DOE/NNSA HSP program managers in monitoring and tracking projects throughout the DOE complex and in responding to inquiries, such as the 2011 request from the President's Commission for the Study of Bioethical Issues that all Federal agencies provide detailed information on all human research projects conducted during the period, 2006 to 2010. The HSRD also serves as a resource for DOE laboratory/site HSPPs looking to identify other sites that are conducting similar research and that therefore may serve as resources. Additionally, outside institutions and members of the public can easily use and search the database.

4.0 Accomplishments and Challenges in FY 2015

Significant program activities and accomplishments in fiscal year (FY) 2015 included:

- DOE quality assurance (QA) consultations at Oak Ridge National Laboratory and Oak Ridge Institute for Science and Education.
- Bi-monthly HSWG calls and one in-person meeting.
- A presentation by DOE at the annual Public Responsibility in Medicine and Research (PRIM&R) meeting in December 2014, showcasing several excellent DOE site HSPPs.
- Annual updating of the HSRD.
- Additional customizations to DOE's electronic protocol tracking (Huron's IRB7) system for use by central DOE and site IRBs. This system helps IRBs to streamline IRB operations and automate end-of-year reporting to the HSRD.
- Development and circulation, for comment/approval, a draft DOE Notice 443.1, *Protection of Human Subjects in Classified Human Subjects Research*.
- Initiation of administrative changes to DOE Order 443.1B, *Protection of Human Research Subjects*, with the goals of: a) harmonizing DOE's definitions with those of research and human subject in the Federal regulations; and b) updating outdated references.
- Initiation of the second term of the Central DOE IRB-C.

In 2015, DOE and other Federal agencies were also given the opportunity to provide input on a Notice of Proposed Rulemaking (NPRM) that will update the 1991 Federal Human Subjects Protection regulations. Within the DOE complex, this process also involved extensive discussions with and reviews by IRB chairs and administrators/managers at the DOE sites and Central DOE IRBs, as well DOE Headquarters program offices and General Counsel.

5.0 Plans and Activities – FY 2016

Priorities in FY 2016 include the following:

- A presentation at the annual PRIM&R meeting in November 2015 on new DOE program initiatives.
- Finalization of administrative changes to the definitions section of DOE Order 443.1B, *Protection of Human Research Subjects*, to harmonize the DOE definitions with those in the Federal regulations.
- Issuance of a new DOE Notice 443.1, *Protection of Human Subjects in Classified Research*.
- Finalization of customizations of IRB7, for DOE's purposes, and additional support to sites implementing IRB7, through training and assistance with the transition.

- Completion and distribution of a checklist to assist DOE sites in reviewing protocols involving large data sets obtained from the internet/social media sites.
- Completion of an effort to update/reorganize the DOE Human Subjects Protection website (<http://science.energy.gov/ber/human-subjects/>) and the listserv for Community IRB members to ensure they are informative and user-friendly.
- Planning for an in-person HSWG meeting in November 2016, and DOE headquarters and DOE site representation and presentations at the PRIM&R meeting.
- Monthly HSWG calls.
- Representation of DOE at various interagency meetings on human subjects research, including the Department of Health and Human Service's Secretary's Advisory Committee for Human Research Protections ([SACHRP](#)).
- An in-person Central DOE IRB meeting (March 2016) and multiple telephone meetings, as well as monthly in-person Central DOE IRB-C meetings.
- Initiation, in January 2016, of the next term of the Central DOE IRB.
- Quality assurance consultation at Sandia National Laboratories, and possible in-person or remote quality assurance consultations at up to two additional DOE sites.
- Collaboration, with the [HHS Office for Human Research Protections](#) and other agencies, in the review of public comments to the NPRM and resolution of those comments and revisions to the Common Rule.

Appendix A
Research Portfolios at DOE Sites and DOE
Headquarters Program Offices

Ames Laboratory

[Ames Laboratory](#), located in Ames, Iowa, is operated by Iowa State University for the DOE Office of Science. Ames' mission is to conduct fundamental research in the areas of physical, chemical, materials, and mathematical sciences and engineering that underlies energy generating, conversion, transmission, and storage technologies, environmental improvement, and other technical areas essential to national needs. Ames' core competencies are in the areas of advanced materials synthesis, characterization and processing, computational and theoretical sciences, environmental characterization, and remediation technologies.

For human subjects research, Ames utilizes the Iowa State University's IRB, but currently no research involving human subjects is being conducted.

Argonne National Laboratory

[Argonne National Laboratory](#) (ANL) is a multi-program laboratory operated by the University of Chicago Argonne LLC for the DOE Office of Science. ANL occupies 1,500 wooded acres about 25 miles southwest of Chicago. As the United States' first national laboratory, chartered in 1946, ANL was given the initial mission of developing nuclear reactors for peaceful purposes. Today, the laboratory has about 2,800 employees and supports more than 200 research projects, ranging from studies of the atomic nucleus to global climate change research.

At present, only a limited number of human subjects research projects are conducted at ANL. The [University of Chicago's Biological Sciences Division Institutional Review Board](#) is the IRB of record. In return, through the ANL IRB coordinator, ANL provides reviewer support for the University of Chicago IRB. This mutually supportive working relationship continues to prove beneficial in providing protections for human subjects in research at both institutions. Additionally, some ANL projects are reviewed by one of DOE's central IRBs.

Brookhaven National Laboratory

[Brookhaven National Laboratory](#) (BNL) is a multipurpose research institution funded primarily by the DOE Office of Science. Located on Long Island, New York, BNL brings world-class facilities and expertise for research in basic and applied science—from the birth of the universe to the sustainable energy technology of tomorrow. BNL is operated and managed by Brookhaven Science Associates, LLC (BSA), a partnership between Research Foundation of State University of New York, on behalf of Stony Brook University, and Battelle, a nonprofit, applied science and technology organization. BNL's almost 3,000 scientists, engineers, and support staff are joined each year by more than 4,000 visiting researchers from around the world.

The Human Subjects Protection Program is supported by the [Office of Research Administration](#). All human subjects research studies conducted at BNL are reviewed and approved by the Stony Brook University IRB, the Committee on Research Involving Human Subjects, or by one of the Central DOE IRBs.

Fermi National Accelerator Laboratory

Fermi National Accelerator Laboratory ([Fermilab](#)), located in Batavia, Illinois, operates one of the most powerful particle accelerators in the world. It was built for high-energy physics research and is funded primarily by the DOE Office of Science.

Additionally, Fermilab has a Neutron Therapy Facility (NTF), which, since 1976, has been available for treating advanced, radio-resistant cancerous tumors. This facility was used to conduct several large National Institutes of Health-funded tumor treatment trials during its first decade of operation. Since the conclusion of the clinical trials, it has been operated under Work for Others (WFO) agreements as a patient treatment facility. More than 3,000 patients have been treated over the years. All clinical trials were reviewed by the IRB of the sponsoring institution. The most recent WFO partner withdrew in 2013 and Fermilab is pursuing a new partnership in order to resume clinical operations and potentially research activities as well.

Any future human subjects research conducted at Fermilab will be reviewed by the sponsoring institution and approved by the Central DOE IRB.

Idaho National Laboratory

In operation since 1949, the mission of [Idaho National Laboratory](#) (INL) is to discover, demonstrate and secure innovative nuclear energy solutions, other clean energy options and critical infrastructure. INL is a multi-program, science-based, applied engineering laboratory, located outside of Idaho Falls, Idaho, and primarily funded by the DOE Office of Nuclear Energy. The laboratory is dedicated to supporting DOE's missions in nuclear and energy research, science, and national defense. INL also provides scientific and engineering solutions to meet the needs of the nation in other aspects of energy supply and national and homeland security. Battelle Energy Alliance, LLC (BEA) is the Management and Operations (M&O) contractor for INL.

INL's human subjects research is predominantly in the areas of human factors, man/machine interface, and survey research. INL has an internal IRB that reviews such research.

Lawrence Berkeley National Laboratory

[Lawrence Berkeley National Laboratory](#) (LBNL) has been a leader in science and engineering research for more than 70 years. Located on 183 acres in the hills above the University of California's Berkeley campus, overlooking the San Francisco Bay, LBNL conducts research across a wide range of scientific disciplines. LBNL is primarily funded by the DOE Office of Science, and key efforts are in fundamental studies of the universe; life sciences, genomics, and quantitative biology; nanoscience; new energy systems and environmental solutions; and the use of integrated computing as a tool for discovery.

LBNL performs or collaborates in a variety of human subjects research projects. These include the in vitro study of the transformation from normal cell growth to cancer; epidemiologic research into the effects of environment, exercise, and other factors on health; and the development of new methods of imaging the human body. The Human Subjects Protection Program at LBNL includes an onsite IRB called the Human Subjects Committee.

Lawrence Livermore National Laboratory

Since its inception in 1952, [Lawrence Livermore National Laboratory \(LLNL\)](#) has embraced its role as a “new ideas” laboratory, focusing on novel concepts and innovative approaches to national security science and engineering. LLNL’s mission is broader than stockpile stewardship, as dangers ranging from nuclear proliferation and terrorism to energy shortages and climate change threaten national security and global stability. The Laboratory’s science and engineering are being applied to achieve breakthroughs for counterterrorism and nonproliferation, defense and intelligence, energy and environmental security. The Laboratory’s mission requires outstanding capabilities in multiple disciplines, including: High-Energy Density Physics: Achieving fusion ignition and burn; High-Performance Computing; Nuclear Science and Technology; Materials Science; Advanced Lasers and Diagnostics; and Engineering Technologies.

Key Facilities and IRB- The Laboratory supports a number of unique facilities that are central to its ability to carry out its national security mission, among them the National Ignition Facility (the largest, most-energetic laser facility in the world), the Terascale Simulation Facility (home to some of the world’s fastest computers), the National Atmospheric Release Advisory Center, the Forensic Science Center, High Explosives Applications Facility, Center for Accelerator Mass Spectrometry, and the Livermore Valley Open Campus. LLNL’s human subjects research is reviewed by the LLNL IRB.

Los Alamos National Laboratory

The mission of [Los Alamos National Laboratory](#) (LANL) is to develop and apply science and technology to ensure the safety and reliability of the U.S. nuclear deterrent; reduce the threat of weapons of mass destruction, proliferation, and terrorism; and solve national problems in defense, energy, environment, and infrastructure. LANL is located in Los Alamos, New Mexico, and was established in 1943 as part of the Manhattan Project. Following World War II and the lab's contributions in developing the atomic bomb to help bring an end to the war, LANL continued its mission to develop and apply science and technology. LANL is operated and managed for DOE/National Nuclear Security Administration (NNSA) by Los Alamos National Security, LLC.

LANL has a long history of research endeavors and accomplishments, which include identifying possible health effects from internal plutonium depositions of former laboratory workers 60 years ago. LANL employees are currently involved with a wide variety of human subjects research projects in categories such as biomedical, behavioral, bioinformatics, genomics, beryllium, national security, cognitive modeling, and biotechnology. Research in many instances is a collaborative effort with many national and international institutions and organizations. Human subjects research conducted by LANL is reviewed by the LANL IRB.

National Renewable Energy Laboratory

The [National Renewable Energy Laboratory \(NREL\)](#) is a multi-program laboratory in Golden, Colorado. It is the primary research laboratory for the DOE Office of Energy Efficiency and Renewable Energy. NREL develops renewable energy and energy efficiency technologies and practices, advances related science and engineering, and transfers knowledge and innovations to address the nation's energy and environmental goals. Some research conducted by NREL is conducted in homes and/or in commercial buildings, and if humans are required in order for the research to be effective, such research is reviewed by an IRB. The Central DOE IRB has reviewed several NREL projects.

National Security Campus

NNSA's [National Security Campus \(NSC\)](#), formerly the Kansas City Plant, was established in 1949 to build nonnuclear components for nuclear weapons. Over the past 60 years, the products manufactured at the KCP have become much smaller and more complex. The facility, which is funded primarily by NNSA, has evolved into a high-tech research production facility that specializes in science-based manufacturing.

Some of the prototypes must be tested on humans prior to large-scale development/manufacturing, and thus the KCP sometimes conducts human subjects research. KCP uses the Central DOE IRBs as its IRBs of record.

Oak Ridge Institute for Science and Education

Oak Ridge Associated Universities ([ORAU](#)) manages the [Oak Ridge Institute for Science and Education](#) (ORISE) contract. Located in Oak Ridge, Tennessee, ORISE conducts scientific initiatives to research health risks from occupational hazards, assess environmental cleanup, respond to radiation medical emergencies, support national security and emergency preparedness, and educate the next generation of scientists.

Human subjects research includes both long-term and short-term studies of health problems at DOE facilities. Studies include the health of former radiation and beryllium workers at DOE plants, as well as international programs supported by DOE. In addition, ORAU organizes and conducts focus groups, interviews, and surveys to determine health education needs of community residents, develops new communication formats for occupational health and safety specifically geared to meet the needs of small business, and studies behavioral issues that impact the workplace, such as human reliability and personnel security.

ORAU manages the single independent IRB in Oak Ridge, the [Oak Ridge Site-wide Institutional Review Board](#) (ORSIRB), which serves all the Oak Ridge Operations contractors that conduct or propose research involving human subjects. The ORSIRB also provides local and site-specific IRB reviews required for projects involving workers at Oak Ridge facilities proposed by institutions not located in Oak Ridge.

Oak Ridge National Laboratory

[Oak Ridge National Laboratory](#) (ORNL), also located in Oak Ridge, Tennessee, is a multi-program science and technology laboratory managed by UT-Battelle, LLC. ORNL is primarily funded by the DOE Office of Science. Scientists and engineers at ORNL conduct basic and applied research and development to create scientific knowledge and technological solutions that strengthen the nation's leadership in key areas of science; increase the availability of clean, abundant energy; restore and protect the environment; and contribute to national security. ORNL also performs other work for the DOE, including isotope production, information management, and technical program management, and provides research and technical assistance to other organizations.

ORNL relies on the ORSIRB, which serves all the Oak Ridge Office contractors that conduct or propose research involving human subjects, as well as one of the Central DOE IRBs for certain projects.

Pacific Northwest National Laboratory

The [Pacific Northwest National Laboratory](#) (PNNL), located in Richland, Washington, is a U.S. Department of Energy Office of Science multidisciplinary national laboratory that provides facilities, unique scientific equipment, and scientists to strengthen U.S. scientific foundations through fundamental and applied research. PNNL's major initiatives are focused on answering critical scientific questions in complex biological, climate, subsurface, chemical, materials, and computing systems. Other PNNL research missions include preventing and countering terrorism and proliferation of weapons of mass destruction, reducing U.S. energy capacity and dependence on imported oil, and reducing the environmental effects of human activities and creating sustainable systems. PNNL is operated by Battelle Memorial Institute for the U.S. DOE. PNNL performs work for DOE as well as in collaboration with other government agencies, universities, and industry.

Human subjects research at PNNL is reviewed by the PNNL IRB and includes work in human biomarker development, bioinformatics, biometrics, cognitive science, human factors, and computational modeling.

Sandia National Laboratories

[Sandia National Laboratories](#) (SNL) is located in Albuquerque, New Mexico, and is a multi-program national security laboratory owned by the U.S. Government and operated by Sandia Corporation, a wholly owned subsidiary of Lockheed Martin Corporation. Sandia Corporation operates Sandia National Laboratories as a contractor for the NNSA.

SNL carries out research and development in the following key areas: 1) **Nuclear Weapons** – Supporting U.S. deterrence policy by helping sustain, modernize, and secure the nuclear arsenal; 2) **Defense Systems & Assessments** – Supplying new capabilities to U.S. defense and national security communities; 3) **Energy & Climate** – Ensuring the stable supply of energy and resources and protection of infrastructure; and 4) **International, Homeland & Nuclear Security** – Focusing on the protection of nuclear assets and nuclear materials and addressing nuclear emergency response and nonproliferation worldwide.

The [Human Studies Board at SNL](#) reviews all human subjects research, which typically fits into three main categories: 1) counter terrorism/homeland security, 2) cognitive modeling and man/machine interface, and 3) biotechnology.

Savannah River Site

The [Savannah River Site](#) (SRS) is a key DOE industrial complex responsible for stewardship of the environment, the enduring nuclear weapons stockpile, and nuclear materials. More specifically, SRS processes and stores nuclear materials in support of national defense and U.S. nuclear nonproliferation efforts. The site also develops and deploys technologies to improve the environment and treat nuclear and hazardous wastes left from the Cold War. The SRS complex covers approximately 310 square miles, encompassing parts of Aiken, Barnwell and Allendale counties in South Carolina, bordering the Savannah River. The site is owned by DOE and operated by Savannah River Nuclear Solutions, LLC (SRNS). Research and development is performed at the [Savannah River National Laboratory](#) (SRNL). SRNL creates, tests, and deploys solutions to the technological challenges facing the site and the nation.

SRS does not conduct basic human research. However, a number of epidemiologic and health studies of SRS workers, former employees, and members of the surrounding communities are currently being performed by outside research institutions such as the National Institute for Occupational Safety and Health. These studies are typically reviewed by the Central DOE IRB. On occasion, other research involving human subjects (e.g., employee surveys, human factors evaluations) is conducted at SRS. Because of the small number of research protocols, SRS is transitioning review of all SRS human subjects research to the Central DOE IRB.

Thomas Jefferson National Accelerator Facility

[Thomas Jefferson National Accelerator Facility \(Jefferson Lab\)](#), located in Newport News, Virginia, is one of multiple national laboratories funded by the DOE Office of Science. The lab conducts basic research of the atom's nucleus using the lab's unique particle accelerator, known as the Continuous Electron Beam Accelerator Facility (CEBAF). Jefferson Lab also conducts a variety of research using its Free-Electron Laser, which is based on the same electron-accelerating technology used in CEBAF.

Currently, Jefferson Lab is participating in a human subjects research project through a Cooperative Research and Development Agreement (CRADA) with the University of Virginia and industry. The CRADA assigned the requirement for the IRB to the University of Virginia (UVA), as UVA will be conducting the clinical trials.

Y-12 National Security Complex

The [Y-12 National Security Complex \(Y-12\)](#), located in Oak Ridge, Tennessee, is a manufacturing facility that plays a vital role in DOE's Nuclear Weapons Complex. Y-12 is primarily funded by NNSA and helps ensure a safe and reliable U.S. nuclear weapons deterrent. It also retrieves and stores nuclear materials, fuels the nation's naval reactors, and performs complementary work for other government and private sector entities.

Y-12 conducts a small number of human subjects research projects and relies on the [Oak Ridge Site-wide Institutional Review Board](#) (ORSIRB) for the review of these projects.

Major DOE Headquarters Programs that Fund Human Subjects Research

A. DOE Office of Health and Safety, AU-10

The Office of Health and Safety establishes worker health and safety requirements and expectations for DOE to ensure protection of workers associated with the hazards of Department operations. The office conducts domestic and international health studies to determine worker and public health effects from exposure to hazardous materials associated with DOE operations. The office also supports current and former DOE worker medical screening programs.

Among the programs funded by this office are the following:

1. The Former Worker Medical Screening Program

As a result of the development and maintenance of nuclear weapons, workers from the DOE or its predecessor agencies may have developed illnesses from exposure to hazardous materials. The [DOE Former Worker Medical Screening Program](#), otherwise known as the Former Worker Program (FWP), was established by the U.S. Congress as part of Section 3162 of the National Defense Authorization Act for Fiscal Year 1993. The legislation called for DOE to provide ongoing medical screening examinations, at no cost, to eligible former DOE and DOE contractor employees every 3 years through a group of dedicated, professional medical experts from unique teams comprised of universities, unions, and commercial organizations with expertise in administering occupational medicine programs. The program's strengths center on the use of independent organizations to administer the medical screenings; aggressive and multi-faceted outreach programs; uniformity of protocol and equity across DOE sites; and a respect for the confidentiality and protection of former worker information and medical screening results.

This program has evolved over the years and now is operated as a service program for any interested former worker from any DOE site. The DOE Office of Health and Safety made a policy decision in recent years to continue to require projects under this program to undergo review by the Central DOE IRB, despite the fact that these projects are no longer traditional human subjects research. IRB review is required because there are multiple separate screening providers involved and DOE wants to ensure that participants receive clear, accurate, and consistent information regarding:

- The purpose of the program;
- The screening tests they will be offered, such as the beryllium lymphocyte proliferation test (BeLPT) and, in some workers, the CT scan for early lung cancer detection;
- The potential implications of their participation in the program; and
- How their data will be protected.

2. Joint U.S.-Japanese Radiation Health Effects Studies of the Japanese Atomic Bomb Survivors

The U.S. DOE and the Japanese Ministry of Health and Welfare jointly fund the [Radiation Effects Research Foundation \(RERF\)](#) in Hiroshima and Nagasaki, Japan. The RERF is believed to have the longest history of

any ongoing international research program, with DOE and its predecessor agencies having provided support since 1947. The principal focus of the RERF research program is the study of the effects of radiation in the atomic bomb survivors of Hiroshima and Nagasaki.

There are over 117 ongoing research protocols, and several fixed cohorts or subcohorts were established to provide epidemiologic and clinical data on the health status and mortality of the survivors and their children, in addition to laboratory-based research studies in the fields of radiobiology, immunology, genetics, and molecular epidemiology that have contributed to the understanding of the mechanisms of disease and cancer induction:

- The *Life Span Study* (including 120,000 individuals, 33 percent of whom are still alive) – investigates mortality and cancer incidence of the A-bomb survivors;
- The *Adult Health Study* (about 23,000 individuals) – provides biennial health exams, health counseling, and collects tissue samples from those who volunteer when they are tested through this study;
- *In Utero Study* (about 3,600 individuals) – examines the lifetime health status of those who were in the womb at the time of bombing;
- *Genetics Studies of Children of Atomic-Bomb Survivors (F₁) Study* (including 77,000 individuals) – determines genetic effects that could be related to parental exposure and mechanisms of radiation effects on developing diseases and cancers. They include the following studies:
 - Mortality and Cancer Incidence (77,000 individuals)
 - Cytogenetic Study (16,000 individuals)
 - Birth Defects (77,000 individuals)
 - Cancer Incidence (77,000 individuals)
 - Chromosome Aberrations (16,000 individuals)
 - Biochemical Genetics Study (24,000 individuals)
 - Molecular Genetics (DNA) (1,000 families; 1,500 individuals)
 - Clinical Examinations (12,000 individuals)

The RERF has a Federal-wide Assurance and two internal IRBs: the Human Investigation Committee and the Ethics Committee for Genomic Research. RERF is responsible for ensuring that both IRBs comply with specific U.S. and Japanese human subjects protection requirements.

3. Joint Russian-U.S. Radiation Health Effects Studies in Russian Nuclear Weapons Production Plant (Mayak) Workers and Downstream Communities

DOE-funded studies on the health effects of radiation exposure [are jointly conducted by U.S. and Russian scientists](#). The studies are primarily conducted at Mayak and the Southern Urals Biophysics Institute (SUBI) in Ozersk and at the Urals Research Center for Radiation Medicine (URCRM) in Chelyabinsk. Participating U.S. researchers include those from Georgetown University (GU), Oak Ridge Institute for Science and Education (ORISE), PNNL, University of Florida (UF), University of Illinois at Chicago (UIC), University of Southern California (USC), and University of Utah (UU). Also involved is the United Kingdom Public Health England (PHE).

DOE funds five studies:

Project 1.1 - Techa River Population Dosimetry (URCRM, PNNL, and UF)
Project 1.2b - Techa River Population Cancer Morbidity and Mortality (URCRM, UIC, and USC)
Project 2.2 – Mayak Worker Cancer Mortality (SUBI, USC)
Project 2.4 – Mayak Worker Dosimetry (SUBI, Mayak, PNNL, UU, and PHE)
Project 2.8 - Mayak Worker Tissue Repository (SUBI and GU)

The cohorts followed in the DOE-funded population studies include:

-The Techa River Cohort (TRC), which consists of 29,719 exposed permanent residents of villages on the Techa River born before January 1, 1950, and who lived in riverside villages up to 120 miles downstream at any time between January 1, 1950, and December 31, 1960;

-The Techa River Incidence Cohort (TRIC), which consists of 17,435 exposed permanent residents of villages on the Techa River born before January 1, 1950, and who lived in riverside villages up to 120 miles downstream at any time between January 1, 1956, and December 31, 1960;

-The East Urals Radioactive Trace Cohort (EURTC), which consists of 14,494 evacuees from the Kyshtym explosion in 1957, as well as 8,000 who remained in the fringes of the plume, for a total of 22,494. Approximately 21,494 persons in the EURT resided in the Chelyabinsk Oblast; 1,000 who resided in Sverdlovsk Oblast are excluded; and

Although Project 1.1 provided the reconstructed doses for the Techa River Offspring Cohort (TROC), which consists of 24,243 persons born to parents in the contaminated villages along the Techa River after the start of the contamination in 1950, this cohort was studied with funding from the European Commission.

The cohort followed in the DOE-funded worker studies is the Mayak Worker Cohort, which consists of 25,757 individuals, 25% of whom were women, who worked any time from 1948 through 1982 in the reactor, radiochemical, plutonium production, or auxiliary plants.

IRB review is conducted both by the Russian scientific institutes (URCRM and SUBI) and also by several of the participating U.S. institutions, depending on the role of the U.S. participating institution in the project.

B. DOE Office of Energy Efficiency and Renewable Energy

The [DOE Office of Energy Efficiency and Renewable Energy \(EERE\)](#) funds research designed to improve the energy efficiency of residential and commercial buildings. EERE funds both universities and outside organizations, as well as DOE's laboratories, to do such work. Those that are managed as human subjects research by DOE are reviewed by the appropriate DOE IRB (either the IRB of the participating DOE laboratory or the Central DOE IRB) or in some cases by the IRB of the participating university or other outside organization.

Appendix B: Resources

[DOE Human Subjects Protection Program website](#)

[DOE implementation of Subpart A of the federal human subjects protection regulations \(the Common Rule\): 10 CFR 745 “Protection of Human Subjects”](#)

[The relevant Federal regulations: 45 CFR 46, “Protection of Human Subjects”](#)

[DOE Order 443.1B, “Protection of Human Research Subjects”](#)

[DOE Requirements for Protecting Personally Identifiable Information \(PII\)](#)

[Nuremberg Code](#)

[Helsinki Declaration](#)

[Belmont Report](#)

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Appendix C: Abbreviations Used in This Report

ANL	Argonne National Laboratory
BEA	Battelle Energy Alliance, LLC
BeLPT	Beryllium Lymphocyte Proliferation Test
BNL	Brookhaven National Laboratory
BSA	Brookhaven Science Associates, LLC
CEBAF	Continuous Electron Beam Accelerator Facility
Central DOE IRB	Central Department of Energy Institutional Review Board
Central DOE IRB-C	Central Department of Energy Institutional Review Board – Classified
CRADA	Cooperative Research and Development Agreement
DOE	Department of Energy
EERE	Energy Efficiency and Renewable Energy (EERE)
EURT	East Urals Radioactive Trace Cohort
FAQ	Frequently Asked Questions
FWP	Former Worker Medical Screening Program
FY	Fiscal Year
GU	Georgetown University
HSPP	Human Subjects Protection Program
HSRD	Human Subjects Research Database
AU	DOE’s Office of Health, Safety, and Security
HSWG	Human Subjects Working Group
HTM	Human Terrain Mapping
IN	DOE’s Office of Intelligence and Counterintelligence
INL	Idaho National Laboratory
IO	Institutional Official
IRB	Institutional Review Board
Jefferson Lab	Thomas Jefferson National Accelerator Facility
LANL	Los Alamos National Laboratory
LBNL	Lawrence Berkeley National Laboratory
LLNL	Lawrence Livermore National Laboratory
M&O	Management and Operations
NIOSH	National Institute for Occupational Safety and Health
NNSA	National Nuclear Security Administration
NPRM	Notice of Proposed Rulemaking
NREL	National Renewable Energy Laboratory
NTF	Neutron Therapy Facility

OHRP	Office for Human Research Protections, U.S. Department of Health and Human Services
ORAU	Oak Ridge Associated Universities
ORISE	Oak Ridge Institute for Science and Education
ORNL	Oak Ridge National Laboratory
PHE	Public Health England
PII	DOE Requirements for Protecting Personally Identifiable Information
PNNL	Pacific Northwest National Laboratory
PRIM&R	Public Responsibility in Medicine and Research
QA	Quality Assurance
RERF	Radiation Effects Research Foundation
SACHRP	U.S. Department of Health and Human Services' Secretary's Advisory Committee on Human Research Protections
SC	DOE's Office of Science
SNL	Sandia National Laboratories
SRNL	Savannah River National Laboratory
SRS	Savannah River Site
SUBI	Southern Urals Biophysics Institute
TROC	Techa River Offspring Cohort
UF	University of Florida
UIC	University of Illinois at Chicago
URCRM	Urals Research Center for Radiation Medicine
USC	University of Southern California
UU	University of Utah
UVA	University of Virginia
WFO/SPP	Work for Others/Strategic Partnership Projects (HSR funded by outside agencies)
Y-12	Y-12 National Security Complex