

U.S. Department of Energy's (DOE) Approach to Protecting Human Participants of its Broad Research Portfolio:

Use of Central and Site IRBs and Active Community IRB Member Engagement

Argonne National

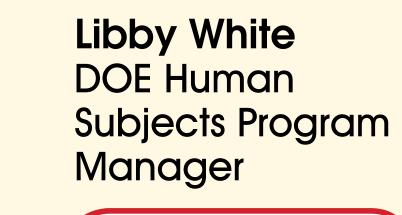
Laboratory

Chicago, IL

Ames Laboratory



John Ordaz NNSA Human Subjects Program Manager





Conducting Human Subjects Research

Ames, Iowa

Argonne

Brookhaven National Laboratory Upton, NY

National Accelerator Laboratory (Fermilab) Batavia, IL

Idaho National Laboratory Idaho Falls, ID

Lawrence Berkeley National Laboratory Berkeley, CA

Lawrence Livermore National Laboratory Livermore, CA

Los Alamos National Laboratory Los Alamos, NM

Oak Ridge Associated Universities Oak Ridge, TN

Oak Ridge National Laboratory Oak Ridge, TN

Pacific Northwest National Laboratory Richland, WA

Sandia National Laboratories Albuquerque, NM

Savannah River Site Aiken, SC





DOE Laboratories

AMES Laboratory

National Laboratory Argonne, Illinois

FERMI

Lawrence Livermore National Laboratory Livermore, CA



Idaho National Laboratory -

Antibody Profiling (ABP (D)

Lawrence Berkeley

Berkeley, CA

National Laboratory

Idaho National

Idaho Falls, ID

Laboratory

Lawrence Livermore National Laboratory – The Marshall Islands Program at LLNL operates three whole body counting facilities which are used to assess public exposures to nuclear fallout contamination in the environment. This program represents the largest per capita whole body counting program in the world for members of the general public.



Pacific Northwest

National Laboratory

Lawrence Berkeley

National Laboratory –

Environment Health and

Safety summer interns

investigate the comfort

for ergonomic pipettes.

Los Alamos National

Sandia National

Albuquerque, NM

Laboratories

Los Alamos National

Low Field Magnetic

Resonance Imaging

Laboratory - Researchers

Magnetoencephalography

are developing an Ultra

Laboratory

Los Alamos, NM

and user preferences

Pacific Northwest National Laboratory - Researchers develop technologies that solve multiple challenges, such as the first-of-its-kind holographic millimeter wave scanner that is being used for security applications as well as in the clothing industry.



Ames Laboratory - Scientists conduct research involving single-molecule immunoassay and DNA screening. The Laboratory utilized the lowa State University Institutional Review Board which reviewed and approved the project.



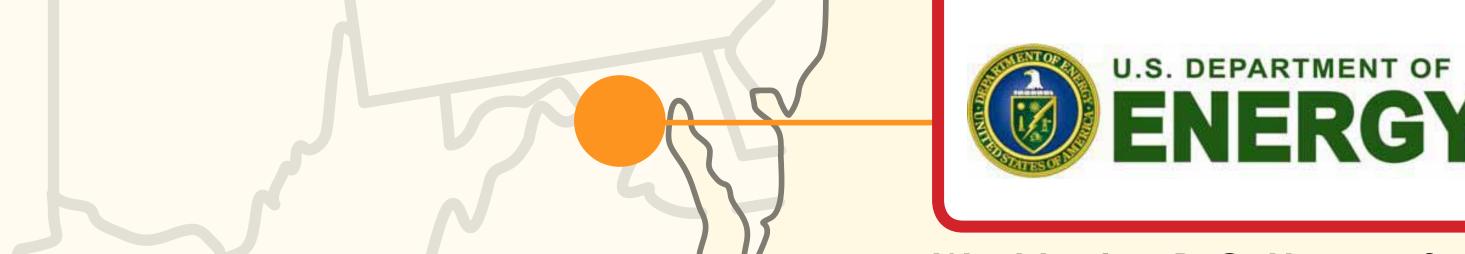
Fermi National Accelerator Laboratory – Neutron Therapy Technician with isocentric and conformal therapy patient in treatment room.

> National Accelerator Laboratory Batavia, IL



Brookhaven National Laboratory - DOE research scientists are examining novel radiotracers in combination with new nuclear medicine imaging techniques to better understand the molecular basis of human diseases including Alzheimer's, Attention Deficit Hyperactivity Disorder (ADHD), obesity, and substance abuse.

Brookhaven National Laboratory Upton, New York



Washington D.C. Human Subjects Protection Program Office

Oak Ridge Associated Universities Oak Ridge, TN

Oak Ridge National Laboratory Oak Ridge, TN

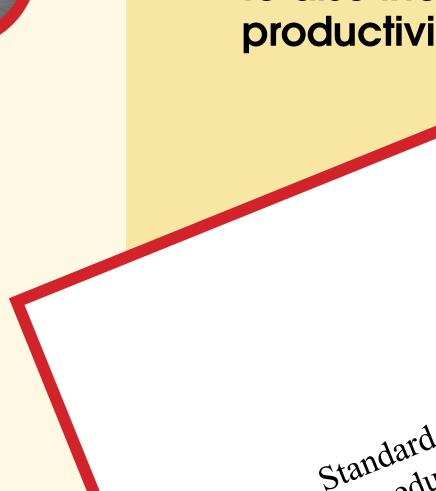
Savannah River Site Aiken, SC



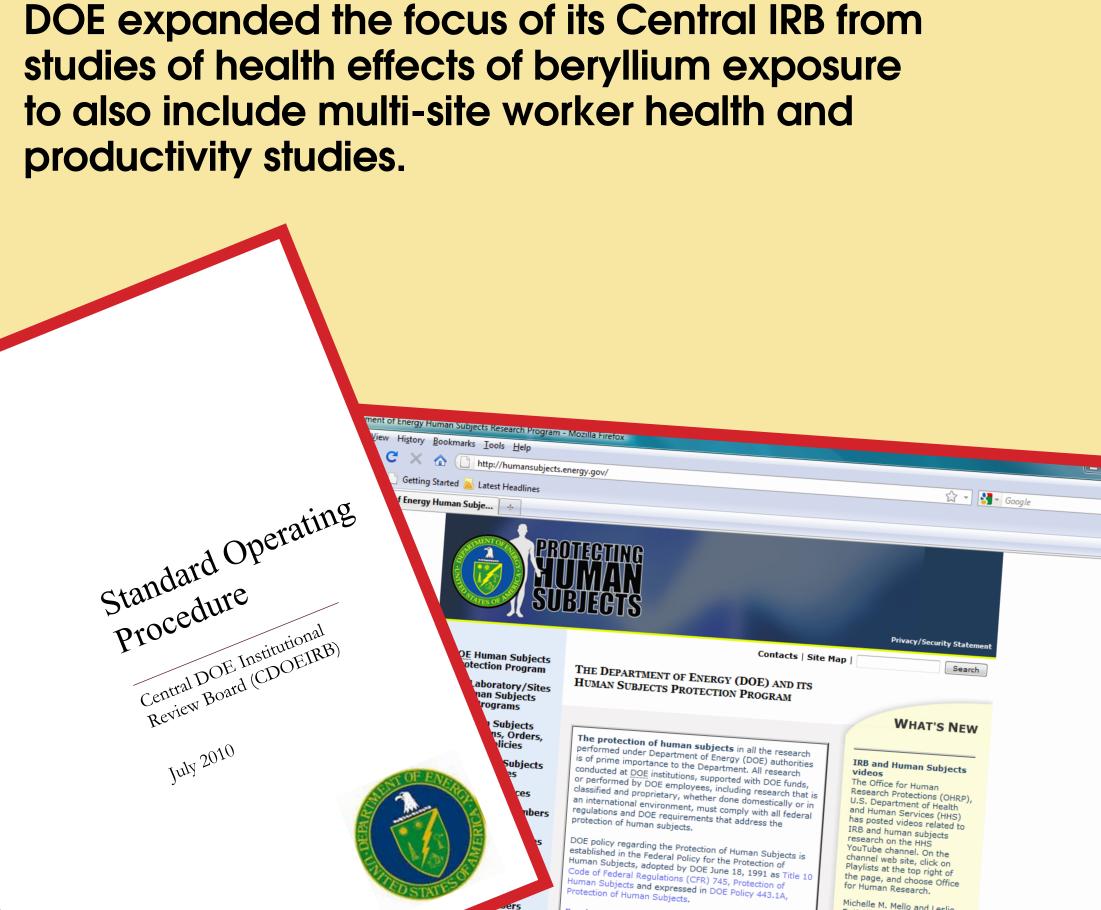
Savannah River Site - Waste certain jobs/exposures.



as Jaguar furnish the decisive mission requirements.



Central DOE IRB



Community IRB Members

as inactive projects, reported by individual sites and research organizations

Organizations with FWP projects include six universities and two research labs.

Former Worker Medical Screening Program (FWP) projects received \$22 million in funding from the D

A total of 1,075,969 human subjects were involved in DOE-funded, site-related, or worker-related projects.
About 49% of human subjects were reported by DOE facilities, and 51% were reported by non-DOE facilities.
The National Institute for Occupational Safety and Health (NIOSH) had the largest number with over 410,000 human subjects, distributed among seven projects. The Oak Ridge National Laboratory (ORNL) had the next largest number of human subjects (over 355,000), with 350,000 in one records analysis project.
The number of human subjects in international projects decreased by 25% from 161,804 in FY2009 to 121,983 in FY2010. One project that ended in FY2009 at the University of Illinois Chicago accounted for the decrease of 40,000 human subjects in international projects.

international projects.

• Human subjects participation in Former Worker Medical Screening Program (FWP) projects dropped by 81% from 68,111 in FY2009 to 13,204 in FY2010. This difference is attributable mostly to the FWP project at the University of Washington-Harborview Medical Center that ended in FY2009 and involved over 54,000 subjects.

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Number of Human Subjects (Total Human Subjects: 1,075,428)

Ridge National Laboratory

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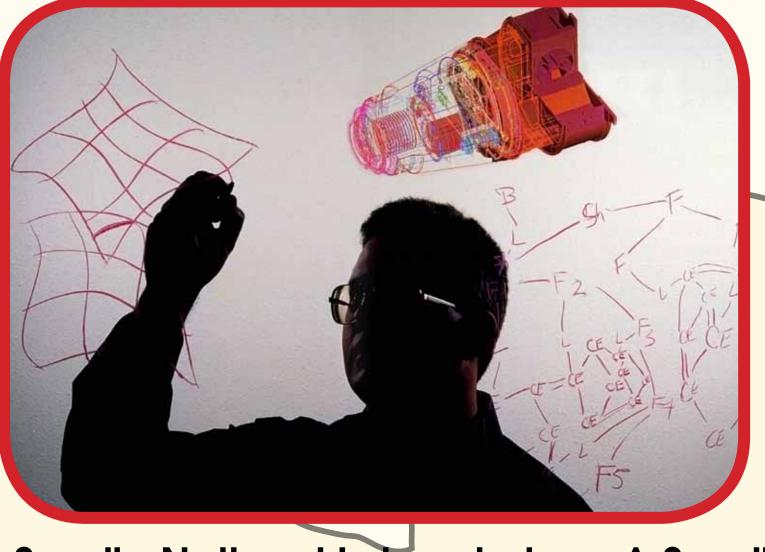
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ens College of the City University of New York

Sandia National Laboratories

DOE and Academia join forces. DOE and the University of Southern California (USC) hosted meeting to prepare, educate, and communicate in a collegial forum.

The DOE also helps community members become successful IRB participants by providing access to resources, training, handson experience, one-on-one mentoring, and networking with other community members.



peak efficiency.

Argonne National Laboratory – Scientists

are developing an "omnivorous engine"

to run on any blend of spark-ignited fuels

suite of sensors evaluates the combustion

inside the engine. The engine controller then

calibrates the engine to burn that fuel at its

such as gasoline, ethanol, or butanol. A

characteristics and chemical signature

Sandia National Laboratories – A Sandia researcher studies how to solve "wicked problems" - complex, rapidly evolving situations with multiple stakeholders and contradictory requirements. Simply engaging a wicked problem changes the nature of the problem itself, introducing a new set of stakeholders with a new set of problems.



Oak Ridge Associated Universities - Medical technologists are analyzing blood samples for sensitivity to beryllium using the Beryllium Lymphocyte Proliferation Test. This lab is one of 5 in the U.S. that performs this test.



remediation. Former workers from this and other DOE sites who may have been exposed to hazardous substances while working at DOE facilities are offered the opportunity to participate in the Former Worker Medical Screening Program, a screening/research program designed as a service to former workers from all DOE sites and also intended to better understand health implications of



Oak Ridge National Laboratory - Where supercomputers such technical edge in human subjects research by quickly analyzing massive data sets to meet critical