

[Close this window](#)

## Institutional Review Board monitors human subjects research

*By Kortny Rolston*

*INL Communications & Governmental Affairs*

Mention the words “human subjects research” and most people conjure images of biomedical experiments or prescription drug trials. They don't think of Idaho National Laboratory.

But some of the lab's research does fall into that category, including a recent energy policy survey, a project on human antibody profiling and a study looking at how exercising with Wii Fit improved the health – and work – of participating INL bus drivers.

In fact, there are currently five projects being monitored by the INL's Institutional Review Board, the committee charged with approving and reviewing human subjects research at the lab.

“Most people think human subjects research just exists in the medical field, but the definition of it is actually quite broad. We've had multiple research projects at INL over the years that were considered human subjects research,” said Dr. Harold Blackman, who leads the seven-person Institutional Review Board.

The INL IRB was created in 1995 to comply with requirements in 10 CFR Part 745, “Protection of Human Subjects,” and DOE Order 443.1, “Protection of Human Subjects.”

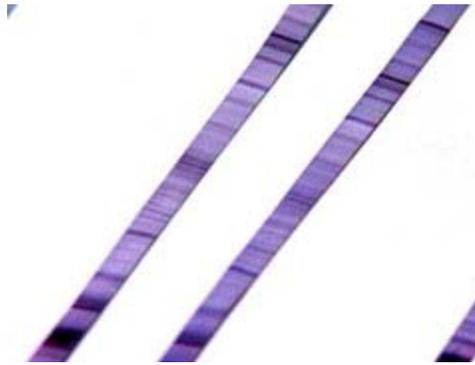
The Department of Energy keeps a Human Subjects Research Database, which is updated yearly and is maintained by Oak Ridge Institute for Science and Education (ORISE) in Tennessee.

It is up to the national labs to monitor projects conducted at INL, supported with INL funds or performed by INL employees, and submit information to the database.



INL scientist Vicki Thompson helped develop a new method of human identification using antibody profiling. INL's Institutional Review Board has monitored the project because it involves human subjects research.

Blackman said most INL scientists and engineers are aware of the IRB, but not all understand what constitutes human subjects research or the process to get it approved.



Using the Antibody Profiling Method as a cost-effective alternative to DNA analysis, scientists compare test strips that highlight individual-specific auto-antibodies — a bar-code-like pattern of proteins unique to each person.

According to DOE, researchers have a legal obligation to protect human subjects if their research involves:

- Private information or general data (including surveys) that are identifiable to specific individuals.
- Tissue, specimens or bodily materials traceable to specific individuals.
- Use of humans to test devices, products or materials developed through research.

DOE requires INL's Institutional Review Board to approve and review all human subjects research. The board has a defined process that is posted on the external INL Web site

at <https://inlportal.inl.gov/portal/server.pt?open=514&objID=7028&mode=2>.

Blackman encourages all INL researchers to read the information in order to better understand what the rules are regarding human subjects research.

"We need to ensure we treat our human subjects appropriately, ethically and within the bounds of the requirements," Blackman said.

A new area of concern for INL's Institutional Review Board (IRB) is human terrain mapping. Human terrain mapping involves gathering intelligence (primarily for the military) about the social, ethnographic, cultural, economic and political elements of the people who live in politically unstable countries. The Department of Energy has mandated INL and the other national labs limit their engagement in human terrain mapping to activities involving only de-identified data. All human terrain mapping activities must be reviewed by the IRB before any work is conducted.

Published: 06/02/2010

[Close this window](#)