



Department of Energy

Washington, DC 20585

April 25, 2013

Dear Laboratory Institutional Officials:

The purpose of this communication is to clarify the DOE requirements for research involving intentional modification of an individual's or a group of individuals' environment, for example through installation of devices in homes and/or through introduction of gases/chemicals to trace airflow in occupied residential, commercial, or public settings.

It is DOE policy that any such DOE-funded or DOE laboratory-managed or conducted projects will be managed as human subjects research and thus will be subject to the requirements of DOE Order 443.1B. Such projects must be reviewed and approved by the Central DOE Institutional Review Board (IRB), a DOE laboratory IRB, or (if conducted by a university) a university IRB with an approved Federalwide Assurance of compliance, prior to the initiation of the research and after consultation with the appropriate Human Subjects Protection (HSP) program manager.

Much of this work is funded by the DOE Office of Energy Efficiency or is work-for-others sponsored by the Department of Homeland Security and other federal agencies. Please feel free to contact me or the HSP program managers with any questions:

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Sincerely,

Handwritten signature of Elizabeth (Libby) White in cursive.

Elizabeth (Libby) White
DOE HSP Program Manager, SC-23.2

Handwritten signature of John Ordaz in cursive.

John Ordaz
NNSA HSP Manager, NA-SH-10

Handwritten signature of Sharlene C. Weatherwax in cursive.

Sharlene C. Weatherwax, Ph.D.
DOE Institutional Official for
Human Subjects Research
Associate Director of Science for
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cc:

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DOE Laboratory IRB Chairs

DOE Laboratory IRB Managers

Central DOE IRB Chair and Co-Managers

Managers, DOE Site Offices