

# Requirements for DOE Program and Project Managers Funding Research Which Involves or May Involve Human Subjects

- 1) Identify projects which will involve: 1) interactions with humans in some way (e.g., through surveys); 2) analysis of their identifiable data or specimens; 3) asking individuals to test devices, products, or materials developed through research; or 4) testing of commercially-available devices in buildings/homes in which humans will be present.
- 2) Ensure that, before tasks involving the above (including preliminary/proof of concept work) are initiated, the institution in receipt of the award has certified that the proposed activity has been reviewed and approved by a DOE IRB (Institutional Review Board/ethics board) and/or, in extenuating circumstances, instead the institution's IRB.
  - a. If the Principal Investigator (PI) works at a DOE lab or will be interacting with DOE lab employees or their data in some way, refer him/her to that lab's IRB.
  - b. If multiple DOE labs or employees (or their data) from multiple DOE labs will be involved, refer the PI to the Central DOE IRB.
  - c. If the PI works at an outside institution that does not have an IRB, refer him/her to the Central DOE IRB.
  - d. If the PI works at a university that has an IRB, and no DOE laboratory researchers or employees/their data will be involved in any way, refer him/her to either the Central DOE IRB (preferably) or the university IRB.

*Note:* The institution receiving the award must have a Federalwide Assurance of compliance in place with the HHS Office for Human Research Protections and must specify in that Federalwide Assurance which IRB(s) are used by that institution. If the Central DOE IRB is used just for purposes of the DOE-funded study, an IRB Authorization Agreement can be put in place between the researcher's organization and DOE. This is a simple process.
- 3) Inform the PI that he/she is responsible for ensuring all subcontractors also comply and also for reporting information on the project annually to the DOE Human Subjects Research Database (HSRD): <https://science.osti.gov/HumanSubjects/Human-Subjects-Database/home>, in accordance with directions provided by the DOE/NNSA Human Subjects Protection Program Managers. *Note:* If a DOE IRB is used, no end of year reporting will be needed.

## Resources

DOE Human Subjects Protection Website: <https://science.osti.gov/ber/human-subjects>

DOE Headquarters Human Subjects Protection (HSP) Program Managers:

-Libby White, DOE HSP Program Manager: [elizabeth.white@science.doe.gov](mailto:elizabeth.white@science.doe.gov), 301-903-7693

-Cheri-Hautala-Bateman, NNSA HSP Program Manager: [cheri.hautala-bateman@nnsa.doe.gov](mailto:cheri.hautala-bateman@nnsa.doe.gov), 202-586-1444

DOE Central and Site IRBs

-Central DOE IRB: contact L. Motz ([Lindsay.motz@orau.org](mailto:Lindsay.motz@orau.org))/J. Hendricks ([Jennifer.hendricks@orau.org](mailto:Jennifer.hendricks@orau.org))

-PNNL: contact Susan Varnum ([susan.varnum@pnnl.gov](mailto:susan.varnum@pnnl.gov))

-LBNL: contact Dianna Bolt ([dgbolt@lbl.gov](mailto:dgbolt@lbl.gov))

-ANL: contact Steve Rupkey ([srupkey@anl.gov](mailto:srupkey@anl.gov))

-BNL: contact Darcy Mallon ([mallon@bnl.gov](mailto:mallon@bnl.gov))

-ORNL/ORISE: contact Lindsay Motz ([lindsay.motz@orau.org](mailto:lindsay.motz@orau.org))

-LLNL: contact Ann-Marie Dake ([dake1@llnl.gov](mailto:dake1@llnl.gov))

-LANL: contact Judy Noles ([jnoles@lanl.gov](mailto:jnoles@lanl.gov))

-Sandia: contact Craig Nimmo ([cenimmo@sandia.gov](mailto:cenimmo@sandia.gov))

-Fermilab: contact Tom Kroc ([kroc@fnal.gov](mailto:kroc@fnal.gov))

-INL: contact Dena Tomchak ([dena.tomchak@inl.gov](mailto:dena.tomchak@inl.gov))