



Department of Energy  
Washington, DC 20585

May 22, 2015

Dear Laboratory Institutional Officials:

The purpose of this communication is to remind DOE sites that DOE considers current or former Federal or contractor employees who become subjects of DOE human subjects research (HSR) to be vulnerable subjects. DOE HSR includes all HSR conducted with DOE funding, at DOE institutions, or by DOE or DOE contractor personnel.

As is stated in the DOE Report, [\*Creating an Ethical Framework for Studies that Involve the Worker Community\*](#), “when workers are the subjects of research, additional care must be exercised to assure that their participation is truly voluntary and that data collected about individual workers are kept confidential...For consent to be informed, participants must have adequate, understandable descriptions of the study purpose, what is expected of them, and any benefits and risks they may experience. For consent to be voluntary, they must not face coercion or reprisal for their decisions.”

Many ongoing projects at DOE sites involving employees as subjects are work-for-others projects that may be sensitive in nature and require that information be close held. It is especially important with these projects to ensure that employees who participate as subjects do so without undue influence or potential repercussions.

Most of your sites already have policies in place to protect employees who become research subjects. New researchers should be informed of these policies and IRBs should be reminded that, in ensuring that the *Criteria for IRB approval of research (as stated in 10 CFR Part 745.111)* are met prior to approving HSR protocols, they should place special emphasis on 10 CFR 745.111 (b) if employees are research subjects.

Section 10 CFR Part 745.111(b) states: “When some or all of the subjects are likely to be vulnerable to coercion or undue influence...additional safeguards have been included in the study to protect the rights and welfare of these subjects.”

Please feel free to contact me or the HSP Program Managers with any questions:

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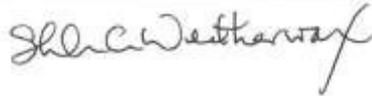
Sincerely,



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