



Department of Energy
Office of Science
Washington, DC 20585

June 23, 2015

Office of the Director

MEMORANDUM FOR: INGRID KOLB
DIRECTOR, OFFICE OF MANAGEMENT

THROUGH: KEVIN T. HAGERTY
DIRECTOR, OFFICE OF INFORMATION RESOURCES

FROM: PATRICIA M. DEHMER
ACTING DIRECTOR, OFFICE OF SCIENCE

SUBJECT: Notice of Intent to Develop a Page Change to DOE Order 443.1B,
Protection of Human Research Subjects

JM CHRONOLOGY
 JM RECEIVED 6/25/15
 OUT FOR REVIEW 7/6/15
 DRB DISCUSSION 7/16/15

PURPOSE: The primary purpose of making the page change is to harmonize the definitions in this Order with those in the Federal regulations for the protection of human subjects (10 CFR Part 745). Specifically, we propose splitting the definition "human subject research" into "research" and "human subject," and adopting, verbatim, the definitions of "research" and "human subject" from 10 CFR Part 745. We also propose adding to this section the definition of "generalizable," since the determination of whether a project is "research" in 10 CFR Part 745 hinges on whether the work being conducted is generalizable. Additionally, we propose making several small corrections and updates to the references, links, and organization titles.

JUSTIFICATION: Changes to the DOE definitions (to adopt the definitions in the Federal regulations) are recommended because the Federal definitions are commonly used and accepted by other agencies and organizations funding our laboratories, as well as the research and human subject protection communities. It also seems like a timely opportunity to correct those sections of the Order that are outdated (as described above). These changes have been discussed with the NNSA Human Subjects Protection Program Manager, and DOE and NNSA are in agreement that they are important to make for clarification purposes.

There are no valid external, consensus, or other Standards available which can be used in place of this directive.

IMPACT: There is no anticipated additional cost or burden on program offices or DOE sites of making the proposed changes.

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^{for}
Ingrid Kolb, Director, Office of Management (MA-1):

Concur:  Nonconcur: _____ Date: 7/15/2015

Unless determined otherwise by the Directives Review Board (DRB), writers will have up to 60 days in which to develop their first draft and submit to the Office of Information Resources, MA-90.

<u>Standard Schedule for Directives Development</u>	<u>Days</u>
Draft Development	Up to 60 days
Review and Comment (RevCom)	30
Comment Resolution	30
Final Review	30
Total	150