



Department of Energy
Office of Science
Washington, DC 20585

Office of the Director

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MEMORANDUM FOR INGRID KOLB
DIRECTOR, OFFICE OF MANAGEMENT
THROUGH: *For* *Camille Behar*
KEVIN T. HAGERTY
DIRECTOR, OFFICE OF INFORMATION RESOURCES
FROM: PATRICIA M. DEHMER *Patricia M. Dehmer*
ACTING DIRECTOR, OFFICE OF SCIENCE
SUBJECT: Notice of Intent to Develop Notice 443.1, *Protection of Human Subjects in Classified Research*

PURPOSE: The purpose for developing this Notice will be to specify additional requirements for the conduct and protection of human subjects, specifically for classified research. This is necessary to ensure legal compliance with the Presidential Memorandum, *Strengthened Protections for Human Subjects of Classified Research*, dated March 27, 1997, commonly referred to as the "Clinton Memo," which the DOE and NNSA offices of General Counsel determined in June 2015 is still in effect and applicable to DOE federal and contractor organizations. The requirements outlined in the Clinton Memo are in addition to those specified in the Federal regulations (10 CFR Part 745) and DOE Order 443.1B, *Protection of Human Research Subjects*.

JUSTIFICATION: This Notice is necessary to expeditiously and effectively communicate and ensure implementation of the legal requirements specified in the Clinton Memo by all DOE organizations and sites funding or conducting classified human subjects research. Even though the Department of Health and Human Services, Office for Human Research Protections (OHRP) was unable to implement a unified program across the "Common Rule" agencies that perform classified research, DOE implemented a limited set of best practices to address the intent of the Clinton Memo. In early 2011, DOE consulted with GC and the informal position was that since the Clinton Memo was never implemented by OHRP, as required, DOE did not see it as applicable. However, in November 8, 2011, the Department of Defense (DoD) issued Instruction 3216.02, which, in essence, implements the Clinton Memo for projects conducted or funded by Defense. Over the last several months DOE had several discussions with DoD concerning DoD sponsored projects at DOE sites, which led DOE to request formal opinions from DOE and NNSA GCs.

In light of the DOE and NNSA General Counsel recent legal opinions that the Clinton Memo is still in effect and is applicable to all DOE federal and contractor organizations, DOE and NNSA need to further strengthen the protection of human subjects in classified research to ensure compliance with the Clinton Memo across the DOE-wide Complex.



REC'D 8/25 2015 C. Behar

The Order follows the unclassified process as described in 10 CFR 745 (Subpart A of 45 CFR 46), for which there is an OHRP Notice of Proposed Rule Making about to be released to revise the current regulations. When the proposed revisions are finalized, the Order will have to be revised accordingly. OHRP has indicated they will soon be working with the Agencies that do classified work to develop a separate subpart to 45 CFR 46, and 10 CFR 745, that will address the Clinton Memo process. Therefore, the two options for the path forward will be to incorporate the Notice into the existing Order or to create a new Order from the Notice just dealing with the classified aspects of the research. At this time, DOE/NNSA believe that a separation of the two processes – unclassified and classified, each with its own Order and regulatory drivers, is the best option. Also, not all of the DOE sites conduct classified research. The drivers for the classified process will be the Clinton Memo and the yet to be developed 45 CFR 46 subpart addressing the Clinton Memo requirements.

The Office of Science is requesting an expedited process for the review and issuance of this draft Notice, in order to assure that the Department can begin the expeditious DOE complex-wide implementation of the critical and legal requirements of the Clinton Memo before the end of the 2015 fiscal year.

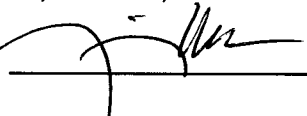
There are no valid external, consensus or other Standards (e.g., ISO, VPP, etc.) available, which can be used in place of this directive.

IMPACT: The proposed Notice implements Presidential legal requirements and does not duplicate existing laws, regulations or national standards and it does not create undue burden on the Department. Almost all of the classified human subjects research is done on behalf of other Federal sponsors under full cost recovery. All DOE Headquarters organizations funding classified human subjects research and DOE sites conducting classified human subjects research will need to ensure that the DOE Institutional Official for Human Subjects Research approves the projects following Institutional Review Board (ethics board) review and approval and prior to initiation of the work. There are other requirements for researchers to keep in mind (e.g., no waiver of consent for classified human subjects research) and for DOE Headquarters organizations to implement (e.g., annual reporting to Office of Science and Technology Policy and publication of DOE's process in the Federal Register).

WRITER: (Elizabeth White, SC-23.2, 3-7693)

OPI/OPI CONTACT: *Office of Biological and Environmental Research, SC-23.2, Elizabeth White, 3-7693*

Ingrid Kolb, Director, Office of Management (MA-1):

Concur:  Nonconcur: _____ Date: 9-3-2015