

Approved: 1-21-2016

SUBJECT: PROTECTION OF HUMAN SUBJECTS IN CLASSIFIED RESEARCH

1. PURPOSE. This notice supplements DOE Order 443.1B and 10 CFR Part 745 by addressing the Department of Energy (DOE)-specific requirements for the protection of human subjects involved in research that is classified, in whole or in part. The DOE requirements and responsibilities for implementing the protection of human subjects involved in research are set forth in DOE Order 443.1B and 10 CFR Part 745. These supplemental requirements and responsibilities for classified human subjects research (HSR) are necessary to ensure compliance with 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 is in effect and applicable to DOE.
2. CANCELLATION. None.
3. APPLICABILITY.
 - a. Departmental Applicability. Except for exemptions in paragraph 3.c., this Notice applies to all Departmental elements.

The Administrator of the National Nuclear Security Administration (NNSA) shall ensure that NNSA employees, contractors, and elements comply with their respective responsibilities under this directive. Nothing in this Notice shall be construed to interfere with the NNSA Administrator's authority under Section 3212(d) of Public Law (P.L.) 106-65 to establish Administration-specific policies, unless disapproved by the Secretary.

In accordance with the responsibilities and authorities assigned by Executive Order 12344, codified at 50 CFR Parts 2406 and 2511, and to ensure consistency throughout the joint Navy/DOE Naval Nuclear Propulsion Program, the Deputy Administrator for Naval Reactors (Director) will implement and oversee requirements and practices pertaining to this Directive for activities under the Director's cognizance, as deemed appropriate.

DOE Contractors. Except for exemptions in paragraph 3.c., the Contractor Requirements Document (CRD), Attachment 1, sets forth the requirements of this Notice that shall apply to contracts that include the CRD. The CRD shall be included in contracts for the management or operation of a DOE-owned or DOE-leased facility (i.e., those contracts that include the clause at 48 CFR Part (DEAR) 970.5204-2, Laws, Regulations, and DOE Directives) that involve classified, in whole or in part, HSR, as defined in DOE O 443.1B, paragraph 7.i., and comprehensively explained in paragraph 4.a. of this Notice, irrespective of the party conducting the classified HSR under the contract. For all other contracts

that involve classified HSR, the applicable requirements set forth in this CRD shall be included in the contract terms and conditions, as appropriate.

b. Exemptions from DOE N 443.1.

Any requests for partial or full exemptions from the requirements of this Notice shall be submitted in writing to the appropriate Human Subjects Protection (HSP) Program Manager (NNSA HSP Program Manager for NNSA projects and DOE HSP Program Manager for all others). An exemption may be recommended to the Secretary or the Secretary's designee by the appropriate HSP Program Manager after concurrence by the DOE Institutional Official (IO) (see paragraph 5.c.). The basis for granting or denying exemption requests shall be set forth in writing.

Exemption. Bonneville Power Administration is exempt from the requirements of DOE N 443.1.

4. REQUIREMENTS. Research using human subjects provides important medical and scientific benefits to individuals and to society. The need for this research does not, however, outweigh the need to protect individual rights and interests. DOE requirements for the protection of human research subjects are specified in DOE O 443.1B; the Federal Policy for the Protection of Human Subjects, 45 CFR Part 46, *Protection of Human Subjects*; and in 10 CFR Part 745, DOE's implementation of Subpart A of 45 CFR Part 46. DOE's additional requirements to ensure classified HSR (which includes research that is classified in whole or in part, whether conducted with DOE funding, at DOE institutions (regardless of funding source), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), and whether done domestically or in an international environment, and regardless of level of classification) complies with the principles of the Clinton Memo are listed below. DOE will publish its process for identifying, reviewing, approving, and monitoring classified HSR in the Federal Register, within 6 months of the issuance of this Notice.

a. Requirements:

- (1) All information related to classified HSR will be managed in accordance with applicable DOE directives and other requirements (e.g., Executive Orders, laws, regulations).
- (2) HSR that is classified, in whole or in part, shall not be initiated without Institutional Review Board (IRB) approval, followed by approval by the DOE Institutional Official (IO). The DOE IO, in consultation with the HSP Program Managers, will determine whether he/she will approve/disapprove the project or brief the Secretary about the project prior to his/her approval/disapproval.
- (3) No waiver of informed consent will be granted.

- (4) The use of the expedited review process by IRBs is prohibited.
- (5) HSR exemptions (as per 10 CFR Part 745.101(b)) will not be used. The fact that research meets a particular exemption category may be noted, but a full IRB review will be required.
- (6) The identity of the sponsoring Federal agency will be disclosed to subjects, unless the sponsor requests that it not be done, because doing so could compromise intelligence sources or methods; the research involves no more than minimal risk to subjects; and the IRB determines that by not disclosing the identity, the investigators will not adversely affect the subjects.
- (7) The informed consent document will state that the project is classified, and what that means for the purposes of that project.
- (8) An IRB must have a voting quorum of at least five members, which must include a non-scientist and an unaffiliated member.
- (9) The unaffiliated member must be a nongovernmental member with the appropriate security clearance. This individual cannot be a current Federal employee or a DOE site contractor.
- (10) Any IRB member can appeal an approval decision to the DOE IO, Secretary of Energy, and Director of the Office of Science and Technology Policy (OSTP), in that order.
- (11) The IRB must determine whether the potential human subjects need access to classified information to make a valid informed consent decision.
- (12) Information on each HSR project that is classified, in whole or in part, and reviewed during that fiscal year, as well as the number of human subjects in each project, must be submitted annually by the responsible DOE IRB, to the DOE and NNSA HSP Program Managers, following the end of the fiscal year and no later than October 15, using the form in Attachment 3. They will compile this information and prepare a summary document, for signature by the DOE IO and delivery to OSTP.
- (13) An IRB that believes that an HSR project that is classified, in whole or in part, can be thoroughly reviewed in an unclassified manner, can submit a request for a waiver from the requirements of this Notice for the purpose of that particular study. The waiver request must be signed by the IRB Chair, and submitted to the appropriate HSP Program Manager for review and approval, using the form in Attachment 2. A list of waiver requests and the actions taken will be provided monthly to the DOE IO.

- (14) It is Departmental policy that classified Human Terrain Mapping (HTM), as defined in DOE O 443.1B, paragraph 7.i., is managed as HSR and if classified, in whole or in part, is subject to the requirements of this Notice, in addition to the requirements specified in DOE O 443.1B, Paragraph 4.a.(2) and its corresponding CRD.
- b. Solicitations. Any solicitation issued by a DOE element for classified HSR that is classified, in whole or in part, shall require compliance with the requirements of this Notice via its CRD, as well as with DOE O 443.1B via its CRD, and 10 CFR Part 745 and 45 CFR Part 46, as applicable.
- c. Contracts and Other Funding Agreements. Any DOE contract involving HSR that is classified, in whole or in part, shall require compliance with the requirements set forth in the CRD associated with this Notice (Attachment 1), DOE O 443.1B and its CRD, 10 CFR Part 745, and 45 CFR Part 46, as applicable. All other DOE funding agreements involving HSR that is classified, in whole or in part, shall also require compliance with this Notice, with DOE O 443.1B, and with 10 CFR Part 745 and 45 CFR Part 46.
- d. Notification. The appropriate HSP Program Manager shall be notified in writing upon award of any new project or modification involving HSR that is classified, in whole or in part, even if it meets the regulatory definition of exempt HSR as outlined in 10 CFR Part 745.101(b). Additional notifications may be required under DOE O 443.1B.
- e. Reporting. A list of HSR projects that are classified, in whole or in part, and have been reviewed during that fiscal year, as well as the number of human subjects in each project, must be submitted annually by the responsible DOE IRB to the DOE and NNSA HSP Program Managers, following the end of the fiscal year, and no later than October 15, using the form in Attachment 3.
- f. Protected Classes. DOE employees/contractors are considered vulnerable subjects and shall be afforded additional protections as determined by the IRB (see Attachment 4).

5. RESPONSIBILITIES.

All DOE employees, contractors, other funding recipients and parties to other DOE agreements share the responsibility to protect the rights and welfare of human subjects of classified research while ensuring proper identification and protection of classified information associated with this research, in accordance with the applicable requirements, including DOE Order 475.2B, *Identifying Classified Information*. The Secretary of Energy is responsible for oversight of the conduct of DOE-related human subject research. The following responsibilities are in addition to those listed in DOE O 443.1B.

- a. Under Secretary for Science and Energy.

- (1) Monitors implementation of this Notice within DOE in accordance with policy established by the Secretary and in consultation with the NNSA, as appropriate.
 - (2) Ensures implementation of human subjects protection measures for classified HSR in accordance with the requirements of this Notice, DOE O 443.1B, 10 CFR Part 745, and 45 CFR Part 46, in consultation with the NNSA.
 - (3) Delegates review and approval of statements of work for classified HTM projects submitted by DOE's non-NNSA sites/projects to the DOE HSP Program Manager.
- b. Under Secretary for Nuclear Security and Administrator of the National Nuclear Security Administration delegates review and approval of statements of work for classified HTM projects submitted by NNSA Sites and NNSA projects to the NNSA HSP Program Manager.
- c. The DOE Institutional Official (DOE IO) is the Senior DOE Official responsible for overseeing and monitoring Departmental implementation of the requirements of this Notice, DOE O 443.1B, 10 CFR Part 745, 45 CFR Part 46, as well as Executive Orders, Presidential Memoranda, and other Presidential directives, in consultation with the NNSA, as appropriate. Under this Notice, the DOE IO is also responsible for: 1) ensuring the Central DOE Institutional Review Board-Classified (CDOEIRB-C) complies with applicable requirements; 2) ensuring the Federalwide Assurance (FWA) and IRB registration for the CDOEIRB-C are properly maintained and current; 3) formally appointing the Chair, Vice-Chair and other CDOEIRB-C members; and 4) approving/disapproving classified HSR, in whole or in part, after IRB approval and prior to initiation. The DOE IO must concur and/or approve on all requests for partial or full exemptions from the requirements of this Notice.
- d. DOE HSP Program Manager.
- (1) Develops procedures for the classified HSP program, in consultation with the NNSA HSP Manager, as appropriate.
 - (2) Drafts, prepares, updates and issues guidance to be followed for obtaining approval for classified HSR in consultation with the NNSA HSP Manager, as appropriate.
 - (3) Reviews/approves (or when an NNSA element is involved, reviews and may recommend approval of) local plans to correct any noncompliance or to mitigate adverse events and unanticipated problems, ensuring they comply with applicable classified HSP requirements.

- (4) Reviews and approves statements of work for classified HTM projects submitted by DOE's non-NNSA sites and/or projects. Ensures compliance with DOE requirements [see paragraph 4.a.(2) of DOE Order 443.1b], and for Strategic Partnership Projects and Strategic Intelligence Partnership Projects, coordinates with appropriate Headquarters leads prior to approving such statements for work for initiation. Ensures Field/Site Offices and M&O contractors are aware of decisions concerning proposed classified HTM work, as appropriate.
- (5) Provides advice and guidance on evolving Departmental and national bioethics and regulatory issues regarding human subjects protection in classified research and helps identify and resolve program/project concerns in consultation with the NNSA HSP Program Manager, as appropriate.
- (6) Conducts biennial institutional performance reviews of all Institutional Review Boards that review classified HSR to assess compliance with human subjects protection requirements, in consultation with the NNSA HSP Program Manager, as appropriate.
- (7) Makes recommendations to the Secretary, after concurrence from, and through the DOE IO, regarding requests for exemptions from the requirements of this Notice, in consultation with the NNSA HSP Program Manager as appropriate.
- (8) Reviews and, in coordination with the NNSA Program Manager and the Office of Intelligence and Counterintelligence, approves requests for waivers, on a project-by-project basis, from the requirements of this Notice, if the IRB determines that a project that is classified, in whole or in part, can be reviewed in an unclassified manner.
- (9) Concurs on HSP provisions for classified research in interagency agreements, in consultation with the NNSA HSP Program Manager, as appropriate.
- (10) Maintains the unclassified list of classified HSR Projects for DOE.

e. NNSA HSP Program Manager.

- (1) When an NNSA element or project is involved, the responsibilities of the NNSA HSP Program Manager are identical to those of the DOE HSP Program Manager.
- (2) Ensures compliance with DOE/NNSA requirements and coordinates with the NNSA Office of Institutional Programs, as appropriate.
- (3) Works with the DOE HSP Program Manager, as outlined in paragraph 5.d.

f. Office of Intelligence and Counterintelligence.

- (1) Reviews and approves, prior to initiation, statements of work for classified HTM projects received from organizations within the intelligence community.
- (2) Reviews and approves statements of work for non-HTM, intelligence-related classified, in whole or in part, HSR prior to initiation.
- (3) In these reviews, prior to approval, coordinates with the appropriate HSP Program Manager.
- (4) Reviews and, in coordination with the DOE and NNSA Program Managers, concurs on requests for waivers, on a project-by-project basis, from the requirements of this Notice, if the IRB determines that the project that is classified, in whole or in part, can be reviewed in an unclassified manner.

g. Secretarial Officers or their Designees.

- (1) Ensure that all proposals for classified research, studies, tests, surveys, surveillance, or other data collection are reviewed to identify HSR that is classified in whole or in part.
- (2) Ensure that any questions or uncertainties regarding the applicability of human subjects protection requirements in classified research to such proposals, and any other issues and concerns regarding the requirements of this Notice, are promptly referred to the appropriate HSP Program Manager for resolution.
- (3) Ensure that the contracting officer is advised when work statements for proposed agreements include HSR that is classified, in whole or in part, to ensure that the CRD or its requirements (as appropriate) are applied to all classified HSR conducted with DOE funding, at DOE institutions, or by DOE personnel under agreements other than site/facility management contracts, such as support services contracts, cooperative agreements, work-for-others agreements, and interagency agreements.
- (4) Ensure that the contracting officer, after being notified of the affected contracts, incorporates the CRD into the affected contracts by way of the Department of Energy Acquisition Regulations (DEAR) Laws, Regulations, and Directives clauses included in those contracts. In the case of contracts or other agreements requiring contractor performance of activities covered by the CRD, but which do not contain the DEAR Laws, Regulations, and DOE directives clause, the contracting officer will work to include the requirements as appropriate.

- (5) Ensure their staffs and field elements comply with the requirements of this Notice, including the notification requirements in paragraph 4.d.
- (6) Ensure relevant personnel actively participate in human subjects protection training and educational programs for classified research.
- (7) Ensure that biennial self-assessments are conducted of those IRBs that review HSR that is classified, in whole or in part, to verify compliance with the requirements of this Notice.
- (8) Ensure appropriate oversight of protection programs for subjects of classified HSR conducted by contractors and through other funding agreements under their cognizance, and other parties to DOE agreements, to ensure compliance with applicable human subjects protection requirements for classified HSR.
- (9) Ensure that the DOE HSP Program Manager and the NNSA HSP Program Manager are involved in negotiating those portions of interagency agreements that address classified HSR.
- (10) Appoint a point of contact for interacting with the appropriate HSP Program Manager on program-related and/or Department-wide issues.

h. DOE Field/Site Offices.

- (1) Ensure contracts and other funding agreements involving HSR that is classified in whole or in part, require compliance with the requirements set forth in the CRD associated with this Notice (Attachment 1), DOE O 443.1B, 10 CFR Part 745, and 45 CFR Part 46.
- (2) Ensure that contractors establish and maintain a process for:
 - (a) Implementing the specific requirements for classified HSR as listed in the CRD;
 - (b) Identifying and reporting classified HTM work according to the requirements of DOE Order 443.1B, its CRD, and this Notice;
 - (c) Notifying the appropriate HSP Program Manager(s) as required in paragraph 1 of the CRD;
 - (d) Implementing guidance provided by the appropriate HSP Manager for classified HSR; and
 - (e) Training relevant personnel in classified HSP training requirements as required by Section u of the CRD to this Notice and DOE Order 443.1B, as applicable.

- (3) Review and provide comments to the HSP Program Manager on the biennial self-assessments or participate in the Headquarters-led Quality Assurance (QA) consultation.

6. REFERENCES.

In addition to those references listed in DOE O 443.1B, references applicable to this Notice include:

- a. Presidential Memorandum, *Strengthened Protections for Human Subjects of Classified Research*, dated March 27, 1997, commonly referred to as the “Clinton Memo” and was published in the Federal Register on May 13, 1997 (62 Fed. Reg.26369).
- b. DOE O 475.2B, *Identifying Classified Information*, dated October 3, 2014, establishes the program to identify information classified under the Atomic Energy Act (Restricted Data (RD), Formerly Restricted Data (FRD), and Transclassified Foreign Nuclear Information (TFNI)] or Executive Order (E.O.) 13526 [National Security Information (NSI)], so that it can be protected against unauthorized dissemination in accordance with legal and Departmental requirements.
- c. DOE O 471.3, *Identifying and Protecting Official Use Only Information*, Admin Change 1, dated January 13, 2011, which establishes a program within DOE and NNSA to identify certain unclassified controlled information as Official Use Only (OUO) (e.g., PII and proprietary information) and to identify, mark, and protect documents containing such information to ensure it is protected according to legal and Departmental requirements.
- d. DOE M 471.3-1, *Manual for Identifying and Protecting Official Use Only Information*, Admin. Change 1, January 13, 2011, which provides detailed requirements to supplement DOE O 471.3.

7. DEFINITIONS.

- a. Refer to DOE O 443.1B for definitions of terms used in human subjects research.
- b. Human Subjects Research. Research (as defined in DOE O 443.1B) involving human subjects (as defined in DOE O 443.1B).
- c. Classified Human Subjects Research – Research involving human subjects that is classified, in whole or in part, in accordance with the Federal sponsor and/or DOE criteria.

8. CONTACT. Questions regarding this Notice should be addressed to the DOE HSP Program Manager, Elizabeth.white@science.doe.gov, Office of Science, Office of Biological and Environmental Research, the NNSA HSP Program Manager,

john.ordaz@nnsa.doe.gov, or kathy.holmes@science.doe.gov, as appropriate.
Information about the DOE HSP Program may be found at
<http://humansubjects.energy.gov/>.

BY ORDER OF THE SECRETARY OF ENERGY:



ELIZABETH SHERWOOD-RANDALL
Deputy Secretary

CONTRACTOR REQUIREMENTS DOCUMENT
DOE N 443.1, *PROTECTION OF HUMAN SUBJECTS IN CLASSIFIED RESEARCH*

Regardless of the performer of the work, the contractor is responsible for compliance with the requirements of this Contractor Requirements Document (CRD).

The contractor is responsible for flowing down the requirements of this CRD to subcontracts at any tier to the extent necessary to ensure the contractor's compliance with the requirements. Only the additional requirements associated with the protection of human subjects in research that is classified, in whole or in part, are listed below. For the basic human subjects research (HSR) protection requirements, refer to DOE O 443.1B. All DOE elements share the responsibility to protect the rights and welfare of human research subjects of classified research while ensuring proper identification and protection of classified information associated with this research, in accordance with the applicable requirements, including DOE Order 475.2B, *Identifying Classified Information*.

Note: Throughout this CRD, the term, "appropriate Human Subjects Protection Program Manager (HSP Program Manager)," refers either to the DOE HSP Program Manager or to the NNSA HSP Program Manager, except where otherwise noted.

In coordination with the contracting officer, the contractor shall—

- a. Notify the appropriate HSP Program Manager
 - (1) Upon award of a contract supporting a project that will involve HSR that is classified, in whole or in part (Note: other notification requirements, listed in the CRD to DOE O 443.1B, may apply);
 - (2) Prior to initiation of any new classified HSR project, even if it meets the regulatory definition of exempt HSR as outlined in 10 CFR Part 745.101(b);
 - (3) Within 48 hours to provide a description of corrective actions taken immediately following an incident involving classified HSR, as well as corrective actions to be taken for concurrence by the appropriate HSP Program Manager. These incidents include, but are not limited to:
 - (a) Any adverse events, unanticipated problems, complaints about the research, and non-compliances, which shall be reported to the institutional review board (IRB) for evaluation for further action with the appropriate HSP Program Manager (*note that unanticipated problems involving loss or possible breach of personally identifiable information must be reported immediately to the IRB and to DOE*); and
 - (b) Any suspension or termination of IRB approval of the research.

- (4) Upon appointment of a new DOE Site IRB Chair or DOE Site Institutional Official that oversees classified HSR.
 - b. Ensure that classified research involving human subjects, regardless of source of funding, is conducted in accordance with this CRD and other applicable requirements (DOE O 443.1B, 10 CFR Part 745 and 45 CFR Part 46, as well as applicable Executive Orders, Presidential Memoranda, and other Presidential and DOE directives, including those addressing classified human subjects research).
 - c. Ensure that the classified HSR is reviewed at intervals appropriate to the degree of risk, but not less than once per year, to assess the risk to test subjects and to ensure the risk is reasonable in relation to anticipated benefits.
 - d. Ensure that contractor-issued solicitations or proposals for research, studies, tests, surveys, surveillance, or other data collection are reviewed to identify HSR that is classified, in whole or in part, and that any resulting agreements include the substance of the requirements in this CRD.
 - e. Ensure no HSR that is classified, in whole or in part, regardless of funding source, conducted at DOE institutions, or by DOE or DOE contractor personnel, whether done domestically or in an international environment, and regardless of the level of classification, is initiated without: 1) IRB approval under the terms of an approved assurance covering the research; and 2) approval by the DOE Institutional Official (IO) after IRB approval and prior to initiation.
 - f. Ensure that no waiver of informed consent is granted.
 - g. Ensure that the use of the expedited review process by an IRB is prohibited.
 - h. Ensure that HSR exemptions [10 CFR 745.101(b)] are not used. The fact that classified HSR meets a particular exemption category may be noted, but a full IRB review will be required.
 - i. Ensure that the identity of the sponsoring Federal agency is disclosed to subjects, unless the sponsor requests that it not be done, because doing so could compromise intelligence sources or methods, and: 1) research involves no more than minimal risk to subjects; and 2) the IRB determines that by not disclosing the identity, the investigator(s) will not adversely affect the subjects.
 - j. Ensure that the fact that the research is classified is disclosed, and that subjects are provided with an explanation of what “classified” means in the context of that project.
 - k. Ensure that the IRB has a voting quorum of at least five members, which must include a non-scientist and an unaffiliated member.
 - l. Ensure that the unaffiliated member is not a current Federal employee or a DOE site contractor.

- m. Ensure that IRB member(s) are aware that they can appeal an approval decision to the DOE IO, Secretary of Energy, and Director of the Office of Science and Technology Policy (OSTP), in that order.
- n. Ensure that the IRB determines whether the potential human subjects need access to classified information to make a valid informed consent decision.
- o. Ensure that each IRB compiles an unclassified list of HSR projects that are classified, in whole or in part, and have been reviewed during that fiscal year, as well as the number of subjects participating in each, and submits the list to the appropriate HSP Program Manager after the close of the fiscal year and no later than October 15, using the form in Attachment 3.
- p. Ensure that the IRB is aware that, if it believes that a funded project that is classified, in whole or in part, can be thoroughly reviewed in an unclassified manner, the IRB can submit a waiver request, signed by the IRB Chair, to the appropriate HSP Program Manager for review and approval, using the form in Attachment 2. Prior to submitting this form and the attachments, the IRB Chair should first contact the appropriate HSP Program Manager to obtain the appropriate secure e-mail address to which to send these documents.
- q. Ensure that DOE employees/contractors, who are considered vulnerable subjects by DOE, are afforded any additional protections determined necessary by the IRB (see Attachment 4).
- r. Ensure that any Human Terrain Mapping (HTM) research that is classified, in whole or in part, complies with DOE requirements specified in this CRD, and also with the specific requirements of the DOE Order 443.1B, Attachment 1 (CRD, Section 5).
- s. Conduct a formal biennial self-assessment (by June 30 of the designated year), and/or participate an informal QA consultation led by the HSP Program Manager, to ensure compliance with the classified HSP Program procedures and other applicable requirements. Self-assessments must be electronically submitted to the appropriate HSP Program Manager, with a copy to the Field/Site Office, and the Office of Intelligence and Counterintelligence.
- t. Submit requests for exemptions from these requirements in writing through the contracting officer to the appropriate HSP Program Manager.
- u. Implement guidance provided by the appropriate HSP Manager for classified HSR.
- v. Ensure relevant personnel actively participate in HSP training and educational programs, specifically as it pertains to classified research.

Attachment 2 - Request for Waiver

This form is to be used if the Institution's IRB believes that a project that is classified, in whole or in part, can be thoroughly reviewed in an unclassified manner. Please have the IRB chair submit a waiver request to the appropriate DOE or NNSA HSP Program Manager for review and approval. Prior to submitting the form via unclassified channels, it will be critical to have a derivative classifier review the form to ensure that classified information will not be disclosed through channels that are not secure. Through classified channels, submit a copy of the classified protocol and/or statement of work, the classified IRB application, and any other materials the IRB determines to be important in making the determination that the project can be reviewed in an unclassified manner.

Project Title: _____

Is the project classified in whole or in part? _____ (Whole/Part)? Classification level: _____

If ongoing project, IRB Initial Approval Date: _____ Site: _____

PI: Name _____ Phone _____ Email _____

Level of risk: _____ (MR, MIMR, OMIMR) (Use: MR - no more than minimal risk; MIMR - minor increase over MR; OMIMR - more than a minor increase over MR)

Rationale for waiver – attach Scope of Work and other relevant documentation:

Requesting IRB Chair: _____ Date: _____

Derivative Classifier: _____ Date: _____

Appropriate Human Subjects Protection (HSP) Program Manager: _____ (NNSA or DOE)

Note: The appropriate HSP Program Manager, in consultation with the other HSP Program Manager and the IN Manager, will determine if a waiver will be granted. A list of waivers granted will be provided monthly to the DOE Institutional Official (IO).

_____ IN Manager	_____ Agree/Disagree with Waiver	_____ Date
_____ NNSA HSPP Manager	_____ Agree/Disagree with Waiver	_____ Date

DOE HSPP Manager

Agree/Disagree with Waiver

Date

Appropriate HSP Program Manager Comments _____

Attachment 4



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:

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

John Ordaz, NNSA HSP Program Manager:
john.ordaz@nnsa.doe.gov; 202-586-0142

UNCLASSIFIED

Sincerely,



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



John Ordaz
NNSA HSP Manager, NA-50



Sharlene C. Weatherwax, Ph.D.
DOE Institutional Official
for Human Subjects Research
Associate Director of Science
for Biological and Environmental Research