

Definition:

Classified Human Subjects Research: The U.S. Department of Energy, Office of Management and Budget, has defined classified human subjects research as research involving human subjects that is classified, in whole or in part, in accordance with the Federal sponsor and/or DOE criteria.

Policy:

Classified and **unclassified** HSR that is funded through the Strategic Intelligence Partnership Program (SIPP) must be reviewed and approved by the Central DOE IRB-Classified.

Procedure:

DOE Order 443.1C, section 14, Classified HSR:

- (a) All information related to classified HSR must be managed in accordance with applicable DOE directives and other requirements (Executive Orders, laws, regulations).
- (b) HSR that is classified, in whole or in part, must not be initiated without IRB approval, which must be followed by DOE IO approval. 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.
- (c) Informed consent may only be waived for classified HSR if the work meets one of the categories of the minimal risk HSR addressed at 10 CFR Part 745.104.
- (d) The use of the expedited review process is prohibited. The fact that research meets a particular expedited category may be noted, but a full IRB review will be required.
- (e) HSR exemptions (as per 10 CFR Part 745.104) will not be used. The fact that research meets a particular exemption category may be noted, but a full IRB review will be required.
- (f) The identity of the sponsoring Federal agency must be disclosed to subjects, unless the sponsor requests it not be done. The only acceptable reason for non-disclosure is that disclosure could compromise intelligence sources or methods. Additionally, the research must be no more than minimal risk, and the IRB must determine that not disclosing the identity will not adversely affect the subjects.
- (g) The informed consent document will state that the project is classified, what that means for the purposes of that project, and what part of the research that applies to. The IRB must determine whether the potential human subjects need access to classified information in order to make a valid informed consent decision.
- (h) When reviewing classified HSR, the unaffiliated member of a DOE or DOE site IRB must be a nongovernmental member (not currently a Federal employee or a DOE site contractor employee) with the appropriate security clearance.
- (i) Any IRB member can appeal* an IRB decision to approve a project to the DOE IO, and if not resolved to the IRB member's satisfaction, to the Secretary of Energy. If still dissatisfied, the IRB member can appeal that approval decision to the Director of the Office of Science and Technology Policy (OSTP) or that Director's

designee, or the Director of National Intelligence (ODNI), or that Director's designee.² The Director of OSTP, or that Director's designee, or the Director of National Intelligence, or that Director's designee will review and approve or disapprove the research, or will convene or designate an IRB that is, to the extent possible, made up of unaffiliated members with the appropriate qualifications and clearance to approve or disapprove the research.

- (j) Information on each HSR project that is classified must be submitted annually, or in accordance with the directions and schedules provided by the appropriate HSP program manager. The HSP program managers will compile this information and prepare a summary document, for signature by the DOE IO and delivery to OSTP and/or ODNI, in accordance with Executive Orders (see Reference 7g.) and other Federal requirements.
- (k) An IRB that believes that an HSR project which is classified, in whole or in part, can be thoroughly reviewed in an unclassified manner, may submit a request for a waiver from some or all of the requirements of this section (specific to classified HSR) for the purpose of that particular study. The study-specific waiver request must be signed by the submitting IRB's Chair(s), and reviewed and approved by the appropriate HSP Program Manager (and if the waiver request relates to an intelligence-related project, also the DOE Office of Intelligence and Counterintelligence (IN)). A list of study-specific waiver requests and the actions taken will be provided monthly to the DOE IO.

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- The Presidential Memorandum, Strengthened Protections for Human Subjects of Classified Research, dated March 27, 1997, requires such an appeal process.

Reference:

United States Department of Energy Order 443.1C, *Protection of Human Research Subjects*, dated November 26, 2019.

Document Review History

Revision Number	Date	Author	Summary of Changes
01	October 2020	Ann-Marie Dake	New