



WORKSHEET: Additional Federal Agency Criteria

The purpose of this worksheet is to provide support for IRB members reviewing research regulated by specific federal agencies. It does not need to be completed or retained.ⁱ

1. Additional Criteria for Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP) (Check if "Yes" or "NA". All must be checked)

- The investigator and research staff are aware of and have been educated about the specific requirements of DOJ research within the BOP.
- The project does not involve medical experimentation, cosmetic research, or pharmaceutical testing.
- The research design is compatible with both the operation of prison facilities and protection of human subjects.
- The investigator will observe the rules of the institution or office in which the research is conducted.
- Investigators who are not BOP employees have signed a statement agreeing to adhere to the requirements of 28 CFR 512.
- All research proposals will be reviewed by the BOP IRB.
- The project has an adequate research design and will contribute to the advancement of knowledge about corrections.
- The selection of subjects within any one organization is equitable.
- Incentives will not be offered to help persuade inmate subjects to participate. Soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are no longer in BOP custody and are participating in authorized research being conducted by BOP employees or contractors.
- If a non-employee of the BOP will receive records in a form not individually identifiable, advance adequate written assurance that the record will be used solely as a statistical research or reporting record has been provided to the agency.
- Except as noted in the consent statement to the subject, the investigator will not provide research information that identifies a subject to any person without that subject's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.
- Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person will not be stored in, or introduced into, an electronic retrieval system.
- Required elements of disclosure include all of the following:

- Anticipated uses of the results of the research.
 - A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
 - A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility.
 - Identification of the investigators.
 - A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a investigator may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.
- The investigator has academic preparation or experience in the area of study of the proposed research.
 - The IRB application includes a statement regarding assurances and Certification required by federal regulations, if applicable.
 - The investigator will assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the Researcher.

2. Additional Criteria for Department of Justice (DOJ) Research Funded by National Institute of Justice (NIJ) (Check if "Yes" or "NA". All must be checked)

- The investigator and research staff are aware of and have been educated about the specific requirements of DOJ research funded by NIJ.
- Projects have a privacy certificate approved by the NIJ human subjects protection officer.
- All investigators and research Staff have signed employee confidentiality statements, which are maintained by the investigator.
- Identification of the funding agency(ies).
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained. For studies sponsored by the NIJ the subject should be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the participants need to be explicitly notified. If the researcher intends to disclose any information, the participant needs to be explicitly informed what information would be disclosed under what circumstances, and to whom. The participant must be informed of any risks that might result from this disclosure and must explicitly provide written consent prior to participating in the research.
- Under a privacy certificate, investigators and research staff do not have to report child abuse unless the subject signs another consent document to allow child abuse reporting.
- A copy of all data will be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

- At least once a year, the researcher shall provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
- At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The researcher shall not include an abstract in the report of findings.
- In any publication of results, the research shall acknowledge the Bureau's participation in the research project.
- The research shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
- Prior to submitting for publication the results of a research project conducted under this subpart, the research shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

3. Additional Criterion for the Environmental Protection Agency (EPA) Research and Research Intended to be Submitted to the Environmental Protection Agency (Check if "Yes" or "NA". All must be checked)

- The research does not involve the intentional exposure of pregnant women, nursing women, or children to any substance.
- If the results of research involving an intentional exposure of human subjects are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA) the IRB's determinations and approval will be submitted to the Environmental Protection Agency (EPA) Human Subjects Research Review official for final review and approval before the research can begin.
- If the research involves children, the research must either be:
 - observational research not involving greater than Minimal Risk or
 - observational research involving greater than Minimal Risk but presenting prospect of direct benefit.
- If the research involves intentional exposure of subjects to a pesticide, the subjects of the research must be informed of the identity of the pesticide and the nature of its pesticidal function.
- If the research involves the use of Broad Consent, the research can only be Exempt under category 7: Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of Identifiable Private Information or Identifiable Biospecimens for potential secondary research.

4. Additional Criteria for Department of Energy (DOE) Research (Check if "Yes" or "NA". All must be checked)

- For research that involves Personally Identifiable Information (PII) or Protected Health Information (PHI), the protocol addresses the following DOE requirements:
 - Keeping PII/PHI confidential.
 - Protecting PII/PHI during storage and transmission.
 - Releasing PII/PHI, when required, only under a procedure approved by the responsible IRB and DOE.
 - Using PII/PHI only for purposes of the IRB-approved project.
 - Handling and marking documents containing PII/PHI as "containing PII or PHI."

- Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII/PHI.
- Making no further use or disclosure of the PII/PHI except when approved by the responsible IRB and DOE, where applicable, and then only under the following circumstances: (a) in an emergency affecting the health or safety of any individual; (b) for use in another research project under these same conditions and with DOE written authorization; (c) for disclosure to a person authorized by the DOE program office for the purpose of an audit related to the project, as required by Office of Management and Budget Circular No. A-133; (d) when required by law; or (e) with the consent of the participant/guardian.
- Protecting PII/PHI data stored on removable media (CD, DVD, USB Flash Drives, etc.), network drives and stand-alone computers using encryption products that are Federal Information Processing Standards (FIPS) 140-2 certified.
- Using passwords to protect PII/PHI used in conjunction with FIPS 140-2 certified encryption products that meet the current DOE password requirements:
 - o Minimum of twelve (12) non-blank characters
 - o Must contain a lowercase letter
 - o Must contain an uppercase letter
 - o Must contain a number or special character
 - o Must contain a nonnumeric in the first and last position
 - o Must not contain the user ID
- Sending removable media containing PII, as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped.
- Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products.
- Accessing data via a secure, encrypted internet connection or through an Electronic Data Interface using TLS 1.1 or newer.
- Sending passwords that are used to encrypt data files containing PII separately from the encrypted data file, i.e. separate e-mail, telephone call, separate letter.
- Using TLS 1.1 encryption methods or higher for websites established for the submission of information that includes PII.
- Using two-factor authentication for logon access control for remote access to systems and databases that contain PII/PHI. (Two-factor authentication is contained in the National Institute of Standards and Technology (NIST) Special Publication 800-63).
- Reporting the loss or suspected loss of PII/PHI immediately upon discovery to (1) the DOE funding office program manager, or, if funded by a DOE laboratory, the DOE laboratory Program Manager and (2) the DOE HSP Program Manager and the NNSA HSP Program Manager. If these individuals are unreachable, immediately notify the DOE-CIRC by phone at 1-866-941-2472, by fax at 702-932-0189, or by e-mail at circ@jc3.doe.gov. For additional information, see: <http://energy.gov/cio/office-chief-information-officer/services/incident-management/jc3-incident-reporting>.
- Classified projects that use PII/PHI must also comply with all requirements for conducting classified research.

For classified human subjects research (in whole or in part):

- Exemptions (as per 10 CFR §745.104) and expedited review cannot be used. If the research meets a particular exemption or expedited category it may be noted, but full IRB review is required.

- A waiver of informed consent may only be granted by the convened IRB for minimal risk research that qualifies for exemption under 10 CFR §745.104.
- 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.
- 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 to make a valid informed consent decision.
- Any IRB member can appeal an approval decision to the DOE IO, Secretary of Energy, Director of the Office of Science and Technology Policy (OSTP) or designee, and then the Director of National Intelligence (ODNI) or designee, in that order. The Director of OSTP (or designee), or the Director of National Intelligence (or 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.
- Information on each project that is classified must be submitted annually (or in accordance with the directions and schedules provided by the appropriate HSP program manager) by the responsible HSP program managers.
- If the IRB believes that the project, in whole or in part, can be thoroughly reviewed in an unclassified manner, a request for a waiver from some or all of the requirements of classified HSR can be submitted. The study-specific waiver request must be signed by the IRB Chair, 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 waiver requests and the actions taken will be provided.
- HSR that is classified, in whole or in part, must not be initiated without IRB approval. After IRB approval, the DOE IO reviews and determines whether he/she will approve/disapprove the project or brief the Secretary about the project prior to his/her approval/disapproval.

For research involving protected classes:

- Prisoners, children, and individuals with impaired decision making [sic] must be conducted in accordance with the appropriate Subpart(s) of 45 CFR §46.
- Proper protections are in place for DOE/NNSA federal and/or contractor employees who may be subject to coercion or undue influence. DOE and DOE site employees are considered vulnerable subjects when participating in research and additional care must be taken to ensure their participation is truly voluntary (e.g., by ensuring they do not report to members of the research team) and that data collected about them is kept confidential.

5. Additional Criterion for Department of Education (ED) Research (Check if “Yes” or “NA”. All must be checked)

If prior consent ⁱⁱ or written documentation of consent or parental permission is waived, the research does NOT involve gathering information about any of the following:

- Political affiliations or beliefs of the student or the student’s parent
- Mental or psychological problems of the student or the student’s family
- Sex behavior or attitudes
- Illegal, anti-social, self-incriminating, or demeaning behavior

- Critical appraisals of other individuals with whom respondents have close family relationships
- Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers
- Religious practices, affiliations, or beliefs of the student or student's parent
- Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)

6. Additional Criteria for Department of Defense (DOD) Research (Check if “Yes” or “NA”. All must be checked)

- The investigator and research staff are aware of the specific DOD requirements and have been educated about these requirements.
- The review has considered (and will document) the scientific merit of the research; within consideration of scientific merit, feasibility, of study completion should be considered. ⁱⁱⁱ
- For research that involves DOD-affiliated personnel, the key investigator must receive approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) to conduct the research.
- For research that takes place on a DOD facility, the key investigator must receive approval from the command or DOD Component HRPP or its delegate responsible for the facility.
- The research does NOT involve Prisoners of war or detainees as subjects. ^{iv}
- The research does not involve the testing of chemical or biological agents, which is prohibited, pursuant to Section 1520a of Title 50, U.S.C, unless exceptions for research for prophylactic, protective, or other peaceful purposes apply,
 - Explicit written approval from DOHRP was obtained prior to the initiation of excepted testing of chemical or biological agents involving HSR.
- Military personnel will not be paid for research conducted while on duty. ^v
- If the research involves DOD-affiliated personnel as subjects, when applicable, the following is required: (Check if “Yes.” Or “NA”. All must be checked):
 - If the research includes risks to their fitness for duty (e.g. health, availability to perform job, data breach), then informed consent form must inform DOD-affiliated personnel about these risks and that they should seek command or Component HRPP guidance before participating.
 - Research involves greater than Minimal Risk: The IRB has appointed an ombudsperson ^{vi} who does not have a conflict of interest with the research or be a part of the research team, and will be present during the recruitment to explain that participation is voluntary and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials. The ombudsman should be available to address concerns about participation.
 - If the study involves Large-scale genomic data (LSGD) collected from DoD-affiliated personnel (including the secondary uses or sharing of de-identified data or specimens) then the following is required:
 - The research is subject to DOD Component security review and DOHRP approval.

- The research will apply an HHS Certificate of Confidentiality
- Administrative, technical, and physical safeguards are considered, as the disclosure of the data may pose a risk to national security.

- If the research is subject to Section 980 of Title 10, U.S.C., consent will be obtained unless waived by the DOHRP.^{vii} The IRB may waive or alter some elements of informed consent for research involving human beings as experimental subjects, so long as it preserves the informed consent of the participant (i.e., the consent indicates that participation in the research is voluntary and the participant/representative is informed of research risks).
 - The key investigator must receive approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) for research that requires a waiver of informed consent pursuant to Paragraph (b) of Section 980 of Title 10, U.S.C.
 - If consent is obtained from the experimental subjects legal representative (for cognitively impaired subjects), the intention of the research must be to be beneficial to the subject^{viii} .
 - Military and civilian supervisors, officers, and others in the chain of command will not influence the decisions of their subordinates regarding participation in research.^{ix}
 - Military and civilian supervisors, officers, and others in the chain of command will not be present at any recruitment sessions or during the consent process for any DoD-affiliated personnel.
 - When a subject is a Service member, all Research Component, and/or National Guard members in a federal duty status are considered to be adults. If a Service Member, Research Component, or Guard member in federal duty status, student at a Service Academy, or trainee is under 18 years of age, the recruitment process and the necessity of including such member as a human subject is considered during IRB review.
 - The disclosure regarding provisions for research-related injury follows the requirements of the DOD component.
 - When conducting multi-site research a formal agreement is required to specify the roles and responsibilities of each party including a Statement of Work (SOW) and specific assignment of responsibilities.
 - Research involving fetal tissue must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.
 - Research or experimentation may not be conducted, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation:
 - May enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or
 - Will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.
 - The risk standard must be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.
- and the key investigator must receive approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) to conduct the research.^x
- If the research involves emergency medicine research, the DOHRP, on behalf of the Secretary of Defense, must approve a waiver of the advance informed consent in accordance with provision 10 USC 980.

- If the research involves Human Subjects who are not U.S. citizens or personnel of the DOD, and is conducted outside the United States, its territories, and its possessions: **(Check if “Yes” or “NA”. All must be checked.)**
 - Applicable national laws and requirements of the foreign country will be followed.
 - When a DoD-affiliated person who is also a citizen of the host nation is a research subject, where differences in applicable standards exist between the United States and the host nation, the standard that is most protective of human subjects will be applied.
 - Take into consideration the cultural sensitivities in the setting where the research will take place ^{xi}.
- For research that is conducted in a foreign country, unless it is conducted by a DOD overseas institution, or involves subjects who are DOD-affiliated personnel that are U.S. citizens, the key investigator must receive approval from the DOD-affiliated personnel’s command or DOD Component Human Research Protection Program (HRPP) to conduct the research.
- When Broad Consent is used, DOHRP notification is required.
- Refer to HRP-833 - WORKSHEET - Considerations for Serving as the sIRB for considerations when serving as the sIRB for a DOD institution.

7. Additional Criteria for Department of Defense (DOD) Research Involving Classified Information ^{xii}
(Check if “Yes” or “NA”. All must be checked)

- The convened IRB approved the research.
- Waivers of consent are prohibited.
- Approval from the DOD-affiliated personnel’s command or DOD Component Human Research Protection Program (HRPP) and DOHRP approval will be obtained. ^{xiii}
- No DoD agency within the Intelligence Community may sponsor, contract for, or conduct non-exempt HSR except in accordance with Paragraph 2.10 of Executive Order 12333 and DoD 5240.01.

ⁱ This document satisfies AAHRPP elements I.1.A, I.1.D, I.1.F, I-2, I-3, I-9, II.2.D, II.2.F-II.2.F.3, II.2.I, II.3.B, II.3.C-II.3.C.1, II.3.E, II.3.F, II.3.G, II.4.A, II.4.B, II.4.C, III.1.C, III.1.E, III.1.F, III.2.C, III.2.D

ⁱⁱ Prior consent means prior consent of the student, if the student is an adult or emancipated minor; or prior written consent of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any survey, analysis, or evaluation funded by the Department of Education.

ⁱⁱⁱ The IRB may rely on outside experts to provide an evaluation of the scientific merit.

^{iv} This includes any person captured, detained, held, or otherwise under the control of DOD personnel (military, civilian, or contractor employee). Such persons include: Enemy Combatant, Lawful Enemy Combatant, Unlawful Enemy Combatant, Enemy Prisoner of War, Retained Person, and Civilian Internee. Such persons do not include personnel of the DOD being held for law enforcement purposes. It does not include persons being held primarily for law enforcement purposes, except where the United States is the occupying power. This prohibition does not apply to activities covered by investigational new drug or investigational device provisions when the purpose is for diagnosis or treatment of a medical condition in a patient. Such treatment (e.g., an investigational new drug) may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to FDA regulations investigational new drugs or investigational medical devices, and only when the same product may be available to DOD-affiliated personnel consistent with established medical practice.

^v Although federal personnel participating as human subjects in DOD-conducted research while on duty may be compensated up to \$50 for each blood draw for scientific and research purposes in connection with the care of any person entitled to treatment at government expense, this IRB allows no such compensation when compensation is otherwise prohibited. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to \$50 for each blood draw. Non-Federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

^{vi} A person who acts as an impartial and objective advocate for human subjects participating in research.

^{vii} Section 980 of Title 10, U.S.C. applies to research financed by DOD appropriated funds. The requirement for consent may be waived by the DOHRP if the following three conditions are met: (1) The research is necessary to advance the development of a medical product for the Military Services. (2) The research may directly benefit the individual experimental subject. (3) The research is conducted in compliance with all other applicable laws and regulations. Research involving a human being as an experimental subject is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects. This definition does not include exempt research involving human subjects.

^{viii} Section 980 of Title 10, U.S.C.

^{ix} ^{ix} If applicable, excluded superiors or those in the chain of command may participate in separate human subjects research recruitment sessions.

^x See: <http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g> (This is the enabling statute for 45 CFR 46.205. Compliance with Subpart B complies with this statute.) See also: <http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g-1>, and <http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g-2>

^{xi} SECNAVINST 3900.39E 29 MAY 2018, Section 3.d.

^{xii} DOD-supported research is considered classified when:

- Classified information is required for IRB review and oversight of the research.
- Classified information must be provided to human subjects, or their guardians, during the HSR recruitment or informed consent process in order to achieve fully effective legal consent.
- Classified information is provided to, or by, research subjects.

DOD-conducted or -supported research is not considered classified when:

- The research is a part of a classified program, but the research itself is not classified; if the information required in the research protocol is not classified; if the information needed by the IRB is not classified; or if the information required by the human subject is not classified. For the purposes of the annual report for classified research, unclassified HSR that falls into the criteria listed in this paragraph should be included in the report.
- Research that requires subjects to hold a clearance as a means of creating ease of entry or access to controlled spaces where the research will occur does not constitute classified HSR unless one of the conditions described in Sections 3.13.b.(1) or (3) also exist.
- If the research constitutes an authorized operation activity, then it is not HSR.

^{xiii} The DOHRP is the final approval authority for all DoD-conducted or DoD-supported classified HSR. The SDO prospectively conducting or supporting the HSR must submit a package to the DOHRP for approval to conduct the classified HSR.