



WORKSHEET: Additional Federal Criteria

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The purpose of this worksheet is to provide support for IRB members reviewing research regulated by specific federal agencies. This worksheet must be used. It does not need to be completed or retained. (LAR = "subject's legally authorized representative")

1 Additional Criteria For Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP) (Check if "Yes" or "N/A". 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, an 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 "N/A". 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.
- The consent document must indicate the funding agency if it is funded by the National Institutes of Justice
- 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.



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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 “N/A”. 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 meets the criteria for either category #1 or #2.
- 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.

4 Additional Criterion for Department of Energy (DOE) Research (Check if “Yes”. All must be checked)

- For research that involves Personally Identifiable Information (PII), the investigator uses the “DOE Institutional Review Board Template for Reviewing Human Subjects Research Protocols that Utilize Personally Identifiable Information (PII)” and the protocol addresses the following DOE requirements:
 - Keeping PII confidential.
 - Releasing PII only under a procedure approved by the responsible IRB and DOE.
 - Using PII only for purposes of the IRB-approved project.
 - Handling and marking documents containing PII as “containing PII or containing Protected Health Information (PHI).
 - Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII.
 - Making no further use or disclosure of the PII except when approved by the responsible IRB(s) 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; (d) when required by law; or (e) with the consent of the participant/guardian.
 - Protecting PII data stored on removable media (CD, DVD, USB Flash Drives, etc.) using encryption products that are Federal Information Processing Standards (FIPS) 140-2 certified.
 - Using passwords to protect PII used in conjunction with FIPS 140-2 certified encryption that meet the current DOE password requirements cited in DOE Guide 205.3-1.
 - 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.
 - 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 FIPS 140-2 certified encryption methods 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. (Two-factor authentication is contained in the National Institute of Standards and Technology (NIST) Special Publication 800-63 Version 1.0.2 found at: <http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-2.pdf>.
 - Reporting the loss or suspected loss of PII immediately upon discovery to (1) the DOE funding office program manager, and (2) the applicable IRBs (as designated by the DOE program manager); if the DOE program manager is unreachable, immediately notify the DOE Joint Cybersecurity Coordination Center.
- For classified human subjects research (in whole or in part):
 - A waiver of informed consent is not granted.
 - Exemptions (as per 10 CFR Part 745.101(b)) and expedited review are not used. If the research meets a particular exemption category it may be noted, but full IRB review is required.
 - 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, and what that means for the purposes of that project.
 - The IRB must have a voting quorum of at least five members, which must include a non-scientist and an unaffiliated member. 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.
 - 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.



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- The IRB must determine whether the potential human subjects need access to classified information to make a valid informed consent decision.
- Information on each project that is classified 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 appropriate form.
- If the IRB believes that the project can be thoroughly reviewed in an unclassified manner, a request for a waiver from the requirements of this Notice can be submitted. The waiver request must be signed by the IRB Chair, and submitted to the appropriate HSP Program
- Manager for review and approval, using the appropriate form. A list of waiver requests and the actions taken will be provided monthly to the DOE IO.
- After IRB approval, the DOE Institutional Official (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.

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

- If prior consent¹ or written documentation of consent or parental permission is waived, the research does NOT involving 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)

¹ 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.



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6 Additional Criteria for Department of Defense (DOD) Research (Check if “Yes” or “N/A”. 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 the scientific merit of the research.ⁱ
- The research does **NOT** involve prisoners of war or detainees as subjects.ⁱⁱ
- Military personnel will not be paid for research conducted while on duty.ⁱⁱⁱ
- Military personnel will not be paid from federal funds for research conducted while off duty.
- If the research involves interventions or interactions with subjects^{iv}, consent will be obtained unless waived by ASD(R&E).^v
- If the research involves interventions or interactions with cognitively impaired subjects, there is anticipated direct benefit to the subject.
- If the research involves Prisoners, the convened IRB reviewed the research. (Review by the expedited procedure is not allowed.)
- Superiors will not influence the decisions of their subordinates regarding participation in research.
- Superiors will not be present at the time of recruitment and consent.^{vi}
- The disclosure regarding provisions for research-related injury follows the requirements of the DOD component.
- When conducting multisite 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.
- If the research involves a survey performed on DOD personnel, DOD approval will be obtained before the research commences.
- Research involving fetal tissue must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g^{vii}.
- If the research involves emergency medicine research, the Secretary of Defense must approve a waiver of the advance informed consent in accordance with provision 10 USC 980.
- For research involving more than Minimal Risk an independent research monitor has been appointed by name who:^{viii} **(Check if “Yes”. All must be checked.)**
 - Has expertise consonant with the nature of risk(s) identified within the research protocol.
 - Is independent of the team conducting the research involving human subjects.
 - Can stop the research, remove individual subjects, and take steps to protect subjects until the IRB assesses the monitor’s report.
 - Will promptly report observations and findings to the IRB or other designated official.
 - Has an IRB approved written summary of duties, authorities, and responsibilities^x based on specific risks or concerns about the research.
 - Has confirmed in writing his/her duties, authorities, and responsibilities.
- If recruitment is in a group setting: **(Check if “Yes”. Either must be checked.)**
 - Research involves greater than minimal risk: The IRB has appointed an ombudsman^x who is unassociated to the research and will be present during the recruitment to monitor that voluntary participation is clearly and adequately stressed and that information provided about the research is clear, adequate, and accurate.
 - Research involves minimal risk: The IRB has discussed and determined whether to appoint an ombudsman based in part on the subject population, the consent process, and the recruitment strategy.
- 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”. All must be checked.)**
 - The permission of the host country has been obtained.
 - The laws, customs, and practices of the host country and the United States will be followed.
 - An ethics review by the host country, or local IRB with host country representation, will take place.

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

- The convened IRB approved the research. (Use of an expedited review procedure is prohibited.)
- The IRB has determined that potential subjects need access to classified information to make a valid, informed consent decision.
- The IRB has consulted with an expert on classified information.
- The research does not involve a waiver of informed consent.
- The informed consent includes a statement that representatives of the DoD are authorized to review research records.
- The informed consent process identifies DOD as the supporting institution of the research, unless the research involves no more than minimal risk or the Secretary of Defense has granted an exception.
- The informed consent includes a statement that the DoD or a DoD organization is funding the study.
- The informed consent process includes a statement that the research is classified and an explanation of the impact of the classification.
- Disclosure or use of classified information complies with the federal requirements for access to and protection of classified information.
- Secretary of Defense approval will be obtained.^{xii}
- Any IRB member who disagrees with a majority decision approving a project will be allowed to appeal the decision to the Secretary of Defense.^{xiii}



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- ⁱ The IRB may rely on outside experts to provide an evaluation of the scientific merit.
- ⁱⁱ 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 the purpose of diagnosis or treatment of a medical condition in a patient. Such treatment (e.g., an investigational new drug) may be offered to detainees with the detainees' informed consent when the medical products are subject to FDA regulations investigational new drugs or investigational medical devices, and only when the same product would be offered to members of the U.S. Military Services in the same location for the same medical condition and only when consistent with established medical practice involving investigational drugs and devices.
- ⁱⁱⁱ 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.
- ^{iv} 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.
- ^v The requirement for consent may be waived by the ASD(R&E) 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. The ASD(R&E) may delegate the waiver authority.
- ^{vi} When applicable, the superiors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session.
- ^{vii} 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>
- ^{viii} The research monitor may be identified by an investigator or appointed by an IRB or IO for research involving human subjects determined to involve minimal risk. There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board. The Heads of the OSD and DOD Components may waive the requirement to have a research monitor on a case-by-case basis when the inclusion of a research monitor is not necessary to provide additional protections for human subjects. This waiver authority may be delegated to a DOD official, as described in the Component's HRPP management plan, but not at or below the position of the institution's DOD IO.
- ^{ix} The duties of the research monitor shall be determined on the basis of specific risks or concerns about the research. The research monitor may perform oversight functions (e.g., observe recruitment, enrollment procedures, and the consent process for individuals, groups or units; oversee study interventions and interactions; review monitoring plans and UPIRISO reports; and oversee data matching, data collection, and analysis) and report their observations and findings to the IRB or a designated official. The research monitor may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research. The research monitor shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report. Research monitors shall have the responsibility to promptly report their observations and findings to the IRB or other designated official.
- ^x The ombudsman may also be the research monitor.
- ^{xi} The IRB needs classified information for approval and oversight, subjects must be provided classified information as part of the consent process; or subjects will provide classified information during the course of the research.
- ^{xii} Submit for approval from the Head of the OSD or DOD Component conducting or supporting the research. Coordinate with the ASD(R&E) and General Counsel of the Department of Defense after the IRB has approved the research.
- ^{xiii} Include the appeal in the submission to the Secretary of Defense.