

OIA-318 WORKSHEET: Additional Federal Criteria

NUMBER	DATE	PAGE
OIA-318	11/09/2023	1 of 4

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

1 Additional Criteria for Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP)¹ (Check if "Yes" or "N/A." All must be checked)²

<input type="checkbox"/>	The investigator and research staff are aware of and have been educated about the specific requirements of DOJ <u>research</u> within the BOP.		
<input type="checkbox"/>	The project does not involve medical experimentation, cosmetic <u>research</u> , or pharmaceutical testing.		
<input type="checkbox"/>	The research design is compatible with both the operation of prison facilities and protection of human subjects.		
<input type="checkbox"/>	The investigator will observe the rules of the institution or office in which the <u>research</u> is conducted.		
<input type="checkbox"/>	Investigators who are not BOP employees have signed a statement agreeing to adhere to the requirements of 28 CFR part 512 .		
<input type="checkbox"/>	All research proposals will be reviewed by the BOP IRB.		
<input type="checkbox"/>	The project has an adequate research design and will contribute to the advancement of knowledge about corrections.		
<input type="checkbox"/>	The selection of subjects within any one institution is equitable.		
<input type="checkbox"/>	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 <u>research</u> being conducted by BOP employees or contractors.		
<input type="checkbox"/>	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 <u>research</u> or reporting record has been provided to the agency.		
<input type="checkbox"/>	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.		
<input type="checkbox"/>	Except for computerized data records maintained at an official DOJ 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.		
<input type="checkbox"/>	Required elements of disclosure include all of the following: <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Anticipated uses of the results of the <u>research</u>. <input type="checkbox"/> 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). <input type="checkbox"/> A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility. </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Identification of the investigators. <input type="checkbox"/> 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. </td> </tr> </table>	<input type="checkbox"/> Anticipated uses of the results of the <u>research</u> . <input type="checkbox"/> 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). <input type="checkbox"/> A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility.	<input type="checkbox"/> Identification of the investigators. <input type="checkbox"/> 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.
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<input type="checkbox"/>	The investigator has academic preparation or experience in the area of study of the proposed <u>research</u> .		
<input type="checkbox"/>	The IRB application includes a statement regarding assurances and certification required by federal regulations, if applicable.		
<input type="checkbox"/>	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 DOJ Research Funded by National Institute of Justice (NIJ) (Check if "Yes" or "N/A." All must be checked)

<input type="checkbox"/>	The investigator and research staff are aware of and have been educated about the specific requirements of DOJ <u>research</u> funded by NIJ.
<input type="checkbox"/>	Projects have a privacy certificate approved by the NIJ <u>human subjects</u> protection officer.
<input type="checkbox"/>	All investigators and research staff have signed employee confidentiality statements, which are maintained by the investigator.
<input type="checkbox"/>	The confidentiality statement on the consent document must state that confidentiality can only be broken if the subject reports immediate harm to subjects or others.
<input type="checkbox"/>	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.
<input type="checkbox"/>	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.

¹ Adapted from [28 CFR part 512](#)

² Implementation of Bureau programmatic or operational initiatives made through a pilot project and conducted with the Bureau of Prisons is not considered to be research.

UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-318 WORKSHEET: Additional Federal Criteria		
	NUMBER	DATE	PAGE
	OIA-318	11/09/2023	2 of 4

3 Additional Criteria for Environmental Protection Agency (EPA) <u>Research</u> and <u>Research</u> Intended to be Submitted to the EPA (Check if "Yes" or "N/A." All must be checked)	
<input type="checkbox"/>	The <u>research</u> does not involve the intentional exposure of pregnant subjects, nursing subjects, or <u>children</u> to any substance.
<input type="checkbox"/>	If the results of <u>research</u> involving an intentional exposure of <u>human subjects</u> are intended to be submitted to or held for inspection by the EPA, the IRB's determinations and approval will be submitted to the EPA Human Subjects Research Review official for final review and approval before the <u>research</u> can begin.
<input type="checkbox"/>	If the <u>research</u> involves <u>children</u> , the <u>research</u> meets the criteria for either category #1 or #2 (OIA-416 CHECKLIST: Children, or equivalent).
4 Additional Criteria for Department of Energy (DOE) <u>Research</u> (Check if "Yes." All must be checked)	
<input type="checkbox"/>	Studies involving <u>human subjects</u> and/or data that will come from more than one site (regardless of how many sites are engaged in the <u>research</u>) must be reviewed by a Central DOE IRB or appropriate other single IRB (sIRB). ³
<input type="checkbox"/>	The checklist for IRBs to use in verifying that HS research protocols are in compliance with DOE requirements, ⁴ or equivalent, submitted by the investigator verifies compliance with DOE requirements for the protection of personally identifiable information.
<input type="checkbox"/>	The checklist (HRP-423) for IRBs to use in verifying that HS research protocols are in compliance with protecting employees who participate as research subjects requirements, ⁵ or equivalent, submitted by the investigator verifies compliance with DOE requirements for the protection of employees who participate as research subjects.
<input type="checkbox"/>	If a study (new or amendment) is reviewed by the convened IRB, there must be at least 5 members present including a scientist, non-scientist, and an unaffiliated member. ⁶ <input type="checkbox"/> N/A, review of renewal or review conducted using the expedited procedure.
5 Additional Criteria for Department of Education (ED) <u>Research</u> (Check if "Yes" or "N/A." All must be checked)	
<input type="checkbox"/>	If prior consent ⁷ or written documentation of consent or parental permission is waived, the <u>research</u> does NOT involve gathering information about any of the following: <ul style="list-style-type: none"> • 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).

³ [DOE Order 443.1C Section 4.a.3](#)

⁴ Obtain current version of "HRP-490-Checklist: Reviewing Protocols that use Personally Identifiable Information" from Lawrence Berkeley National Laboratory (LBNL) IRB.

⁵ [HRP-423-Checklist: Protecting Employees Who Participate as Research Subjects \(osti.gov\)](#)

⁶ [DOE Order 443.1C Section 4.a.9](#)

⁷ 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.

UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-318 WORKSHEET: Additional Federal Criteria		
	NUMBER	DATE	PAGE
	OIA-318	11/09/2023	3 of 4

6	Additional Criteria for Department of Defense (DOD) Research (Check if “Yes” or “N/A.” All must be checked) ⁸
<input type="checkbox"/>	The investigator and research staff are aware of the specific DOD requirements listed in the <i>OIA-103 IRB Handbook</i> , <i>OIA-024 SOP: Reportable Events</i> , and further defined by the <u>research</u> , and have been educated about these requirements.
<input type="checkbox"/>	The review has considered the scientific merit of the <u>research</u> . ⁹ (<i>OIA-320 WORKSHEET: Scientific or Scholarly Review</i> , or equivalent)
<input type="checkbox"/>	The <u>research</u> does NOT involve prisoners of war or detainees as subjects. ¹⁰
<input type="checkbox"/>	DOD-affiliated personnel will not be paid for <u>research</u> conducted while on duty, except for blood draws. ¹¹
<input type="checkbox"/>	If the <u>research</u> involves no more than <u>minimal risk</u> , the IRB may alter or waive required elements of informed consent so long as the consent process is preserved. ¹²
<input type="checkbox"/>	If the <u>research</u> involves greater than <u>minimal risk</u> , consent will be obtained unless waived by DOD Officer for Human Research Protections (DOHRP) or its delegate. ¹³
<input type="checkbox"/>	If consent will be obtained from a legally authorized representative, there is anticipated direct benefit to the subject.
<input type="checkbox"/>	Superiors ¹⁴ will not influence the decisions of their subordinates regarding participation in <u>research</u> .
<input type="checkbox"/>	Superiors ¹⁵ will not be present at the time of recruitment and consent. ¹⁶
<input type="checkbox"/>	If recruitment is in a group setting: (Check if “Yes.” Either must be checked) <input type="checkbox"/> <u>Research</u> involves greater than <u>minimal risk</u> : The IRB has appointed an ombudsman ¹⁷ who 1) must not have a <u>conflict of interest</u> with the <u>research</u> or be a part of the research team; 2) must be present during the <u>human subjects research</u> (HSR) recruitment, monitoring that the recruitment and informed consent explain that participation is voluntary and that the information provided about the <u>research</u> is consistent with the IRB-approved script and materials, including digitally provided materials; and 3) should be available to address DOD-affiliated personnel’s concerns about participation. <input type="checkbox"/> <u>Research</u> involves <u>minimal risk</u> : 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.
<input type="checkbox"/>	<u>Research</u> involving fetal tissue must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g ¹⁸ and the DOD component has provided evidence of completing their Component Level Administrative Review (CLAR).
<input type="checkbox"/>	If the <u>research</u> involves <u>human subjects</u> who are not U.S. citizens or personnel of the DOD, and is conducted outside the United States, its territories, and its possessions, the DOD component has provided evidence of completing their CLAR.
<input type="checkbox"/>	If the <u>research</u> involves a service member, Reserve Component or National Guard member in federal duty status, student at a Service Academy, or trainee who is under 18 years of age, the IRB has considered the recruitment process and necessity of including such member as a <u>human subject</u> in this <u>research</u> .
<input type="checkbox"/>	If the <u>research</u> involves Large Scale Genomic Data (LSGD) ¹⁹ collected from DOD-affiliated personnel, the study must have a certificate of confidentiality in place.

⁸ There might be specific DOD educational requirements or certification required by different DOD components and the DOD component may evaluate the education policies to ensure the personnel are qualified to perform the research based on the complexity and risk of the research.

⁹ The IRB may rely on outside experts to provide an evaluation of the scientific merit.

¹⁰ 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 for the purpose of diagnosis or treatment of a medical condition in a patient. Such treatment may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to Title 21, CFR, and only when the same product may be available to DOD-affiliated personnel consistent with established medical practices.

¹¹ DOD-affiliated 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. DOD-affiliated personnel while on duty and non-DOD-affiliated persons may be compensated for blood draws for research up to \$50 for each blood draw. Non-DOD-affiliated persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

¹² Preservation of the consent process means that subjects are prospectively asked whether they want to participate in the research, the consent indicates the subject’s participation in the research is completely voluntary, and the consent includes the requirement that the subject is informed of research risks. These three elements are required for all studies. Additional elements may be necessary depending on the study characteristics.

¹³ The requirement for consent may be waived by the DOHRP or delegate if the following three conditions are met: (1) The research is necessary to advance the development of a medical product necessary to the DOD. (2) The research may directly benefit the individual experimental subject. (3) The research is conducted in compliance with all other applicable laws and regulations.

¹⁴ Superiors refers to military and civilian supervisors, officers, and others in the chain of command.

¹⁵ Superiors refers to military and civilian supervisors, officers, and others in the chain of command.

¹⁶ When applicable, the superiors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session.

¹⁷ The ombudsman may also be the research monitor.

¹⁸ See: [US CODE-2021-title42-chap6A-subchapIII-partH-sec289g](#) (This is the enabling statute for [45 CFR 46.205](#). Compliance with Subpart B complies with this statute.) See also: [US CODE-2021-title42-chap6A-subchapIII-partH-sec289g-1](#) and [US Code-2021-title42-chap6A-subchapIII-partH-sec289g-2](#)

¹⁹ Large scale genomic data (LSGD) means data derived from genome-wide association studies; single nucleotide polymorphisms arrays; genome sequencing; transcriptomic, metagenomic, epigenomic analyses; and gene expression data; etc. Research involving LSGD may or may not also constitute HSR. Examples of research involving LSGD include, but are not limited to, projects that involve generating the whole genome sequence data for more than one gene from more than 1,000 individuals, or analyzing 100 or more genetic variants in more than 1,000 individuals.

NUMBER	DATE	PAGE
OIA-318	11/09/2023	4 of 4

If the research involves DOD-affiliated personnel, the informed consent document must include, if applicable, potential risks for the revocation of clearance, credentials, or other privileged access or duty. **(N/A, if consent is waived)**