REVISIONS FROM PREVIOUS VERSION

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| Version | Date | Revisions |
| R00 | 3/25/14 | Original issue |
| R00 | 9/8/17 | Annual review, no changes |
| R01 | 11/25/19 | Add revision table, update logo |
| R01 | 12/16/20 | Annual review, no changes |
| R01 | 12/16/21 | Annual review, no changes |
| R01 | 11/17/22 | Annual review, no changes  |
| R02 | 1/13/23 | Annual review, added criteria for DoJ, ED, and DoD |
| R02 | 11/16/23 | Annual review, no changes  |

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| 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)
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| [ ]  | 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. |
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| 1. 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)
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| [ ]  | 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 confidentiality statement on the consent document must state that confidentiality can only be broken if the subject reports immediate harm to subjects or others.  |
| [ ]  | 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. |
| [ ]  | For National Institute of Justice (NIJ)-funded research the consent document must disclose the name(s) of the funding agency(ies). |
| [ ]  | For research conducted within the Bureau of Prisons required elements of disclosure include the identity of the investigators. |
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| 1. 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)
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| [ ]  | 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. |
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| 1. Additional Criterion for Department of Energy (DOE) Research (Check if “Yes”. All must be checked)
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| [ ]  | The “Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with Department of Energy (DOE) Requirements” submitted by the investigator verifies compliance with Department of Energy requirements for the protection of Personally Identifiable Information. |
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| 1. Additional Criterion for Department of Education (ED) Research (Check if “Yes” or “N/A”. All must be checked)
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| [ ]  | If prior consent[[1]](#footnote-1) 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)
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| [ ]  | For certain research not directly funded by the ED and conducted in a school that receives funding from the ED: The IRB must verify compliance with the ED regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:* The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student.
* Any applicable procedures for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received.
* The right of a parent of a student to inspect, upon the request of the parent, any instructional material used as part of the educational curriculum for the student.
* Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
* The administration of physical examinations or screenings that the school or agency may administer to a student.
* The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.
* The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student.

Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received. |
| [ ]  | Access to instructional material used in a research or experimentation program:* All instructional material--including teachers' manuals, films, tapes, or other supplementary instructional material--which will be used in connection with any research or experimentation program, or project must be available for inspection by the parents or guardians of the children engaged in such research.
* Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.

Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law. |
| [ ]  | **Students, are allowed to inspect their education records and limit others from reviewing that information without their permission, unless allowable as described below.*** School officials and SUNY System Administration with a legitimate educational interest in the records.
* Appropriate parties in a health or safety emergency. This includes educational records as well as directory information, and/or personally identifiable, non-directory information with or without student consent.
* Potential schools where you intend to enroll.
* Officials with a subpoena or permission due to a judicial order.
* Organizations providing financial aid to the student (parent payments are not included here).
* Officials complying with federal, state or local audits or compliance investigations.
* Government entities with a legitimate need for the records (ie, IRS, military recruiters, etc.)

• An educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to: * Develop, validate, or administer predictive tests.
* Administer student aid programs.
* Improve instruction.

• A school district or postsecondary institution that uses this exception is required to enter into a written agreement with UB or investigator conducting the research that specifies: * The determination of the exception.
* The purpose, scope, and duration of the study.
* The information to be disclosed.
* That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in 34 CFR 99.31(a)(6) on re-disclosure and destruction of information.
* That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of UB with legitimate interests.
* That UB is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
* The time period during which UB must either destroy or return the information.

Education records may be released without consent under FERPA if all personally identifiable information has been removed including: * Student’s name and other direct personal identifiers, such as the student’s social security number or student number.
* Indirect identifiers, such as the name of the student’s parent or other family members; the student’s or family’s address, and personal characteristics or other information that would make the student’s identity easily traceable; date and place of birth and mother’s maiden name.
* Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.

Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.  |

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| 1. Additional Criteria for Department of Defense (DOD) Research (Check if “Yes” or “N/A”. All must be checked)
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| [ ]  | 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.[[2]](#endnote-1) |
| [ ]  | The research does **NOT** involve prisoners of war or detainees as subjects.[[3]](#endnote-2) |
| [ ]  | Military personnel will not be paid for research conducted while on duty.[[4]](#endnote-3) |
| [ ]  | Military personnel will not be paid from federal funds for research conducted while off duty. |
| [ ]  | If the research involves interventions or interactions with subjects[[5]](#endnote-4), consent will be obtained unless waived by ASD(R&E).[[6]](#endnote-5) |
| [ ]  | 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 following must be checked:[ ]  A convened IRB reviewed the research. (Review by the expedited procedure is not allowed).[ ]  The research complies with 45 CFR 46 Subpart C or meets permissible waiver criteria for epidemiological research. (See HRP 415: Checklist: Prisoners).  |
| [ ]  | If a subject becomes a prisoner, and the protocol was not reviewed and approved by the IRB in accordance with 45 CFR 46 Subpart C the following must be checked:[ ]  The investigator must promptly notify the IRB.[ ]  For DOD conducted research, the Human Protections Director must notify the COHRP.[ ]  For DOD supported research, the non-DOD organization must notify the DOHRPO and other federal agencies.[ ]  The DOHRP must concur with the IRB before the subject can continue to participate while a prisoner. |
| [ ]  | 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.[[7]](#endnote-6) |
| [ ]  | 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. |
| [ ]  | If pregnant women are involved in the research, one of the following must be checked:[ ]  The research does not involve greater than minimal risk [ ]  When the research is greater than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates a subjects, the research complies with 45 CFR 46 Subpart B, except the phrase “biomedical knowledge is replaced with “generalizable knowledge.” (See HRP 412: Checklist: Pregnant Woman, HRP 413: Checklist: Non-Viable Neonates, HRP 414: Checklist: Neonates of Uncertain Viability) |
| [ ]  | Research involving fetal tissue must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g[[8]](#endnote-7). |
| [ ]  | For greater than minimal risk research, consent documents must include the disclosure that subjects may, for the duration of the study, be eligible for health care services for research-related injuries at a military treatment facility, and this eligibility for health care services extends beyond subjects’ participation in the study to such time after the study has ended.Subjects will receive medical treatment if they are injured or become ill as a result of the study. Their doctor will explain the treatment options to them and tell them where they can get treatment. The University at Buffalo makes no commitment to provide free medical care or payment for any unfavorable outcomes that result from their participation in this research. Medical services will be billed at the usual charge and will be their responsibility or that of their third-party payer but they are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research including The University at Buffalo. |
| [ ]  | If children are involved in the research, the research complies with 45 CFR 46 Subpart D. (See HRP 416: Checklist: Children). Service members and all Reserve Component and National Guard members in a federal duty status are considered to be adults. |
| [ ]  | 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[[9]](#endnote-8) 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 DoD-affiliated personnel as subjects, in addition to the basic and required consent disclosures, consent documents must include: **(Check if “Yes”. All must be checked.)**[ ] If the research involves risks to their fitness for duty (e.g., health, availability to perform job, data breach), the informed consent document (ICD) must inform DoD- affiliated personnel about these risks and that they should seek command or component guidance before participating.[ ]  If applicable, a statement of potential risks for the revocation of clearance, credentials, or other privileged access or duty.[ ]  A statement that the DoD or a DoD organization is funding the study[ ]  A statement that representatives of the DoD are authorized to review research records. |
| [ ]  | If the research involves a human being as an experimental subject and is supported by DoD-appropriated funds, informed consent must be obtained from the subject in advance, in accordance with 10 USC 980. If the subject is unable to provide informed consent and consent will be obtained in advance from the subject’s legal representative, the research must be intended to benefit the individual subjects. |
| [ ]  | 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. |
| [ ]  | A description of who is responsible and the process used to promptly (AAHRPP defines “promptly” as within 30 days) report to the Component Office of Human Research Protections (COHRP).[ ] Reports of audits of DoD-conducted or DoD-supported human participant research by another federal or state agency, official governing body of a Native American or Alaskan native tribe, other official entity, or foreign government. CONFIDENTIAL Page 9 November 11, 2022.[ ]  Allegations of serious or continuing noncompliance related to research involving human subjects that are substantiated by investigation, and subsequent actions taken based on the findings.[ ]  Substantiated allegations related to classified HSR must be reported immediately. |
| [ ]  | Civilian investigators attempting to access military volunteers should seek collaboration with a military investigator familiar with service-specific requirements. |
| [ ]  | A description of the process to confirm approval by the appropriate DoD component prior to research starting, including who is responsible and the process they go through. DoD component-level administrative review (CLAR) must be conducted when: * Human subjects research is conducted in a foreign country, unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are US citizens.
* The research requires a waiver of informed consent pursuant to 10 USC 980, Subsection (b).
* The research is fetal research, as described in 42 USC 289g-289g-2.
* Large scale genomic data (LSGD) is collected from DoD-affiliated personnel. LSDG includes data derived from genome-wide association studies; single nucleotide polymorphisms arrays; genome sequencing; transcriptomic, metagenomic, epigenomic analyses; and gene expression data; etc. (See definition in DoDI 3216.02 G.2 Definitions)
* The research constitutes classified research involving human subjects (DoDI 3216.02 section 3.13).
* The research is required to be approved by the DOHRP (in addition to the COHRP) in accordance with DoDI 3216.02.
* Component review includes review of reliance agreements.
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| [ ]  | * When UB is notified by any federal body, state agency, official governing body of a Native American or Alaskan native tribe, other entity, or foreign government that any part of an HRPP is under investigation for cause involving a DoD-supported research protocol.
* Any problems involving risks to subjects or others, suspension or termination of IRB approval, or any serious or continuing noncompliance pertaining to DoD-supported human subject research.
* The results of the IRB’s continuing review, if required.
* Change in status when a previously enrolled subject becomes pregnant, or when the investigator learns that a previously enrolled subject is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with 45 CFR 46, Subpart B.
* Change in status when a previously enrolled subject becomes a prisoner, and the protocol was not reviewed and approved by the IRB in accordance with 32 CFR 219, Subpart C.
* Closure of a DoD-supported study.
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| [ ]  | * When following Department of Defense (DOD) regulations and requirements:
	+ Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD after the research protocol is reviewed and approved by the IRB. When a survey crosses DoD Components, additional review is required.
	+ For DOD supported research, the following must be promptly (within 30 days) reported to the DOD human research protection officer:
		- When significant changes to the research protocol are approved by the IRB.
		- The results of the IRB continuing review.
		- Change of reviewing IRB.

When the organization is notified by any Federal department, agency or national organization that any part of an HRPP is under investigation for cause involving a DOD-supported research protocol. |
| [ ]  | • If non-exempt research is supported by DoD-appropriated funds and involves experimental subjects as defined in DODI 3216.02, consent must be obtained in advance, in accordance with 10 USC 980. * An 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 subject (i.e., the consent indicates that participation in the research is voluntary and the subject/representative is informed of research risks).

• DOHRP may waive the requirements for prospective consent for research involving human beings as “experimental subjects” when all of the following are met: * (A) The research is necessary to advance the development of a medical product for the Military Services.
* (B) The research may directly benefit the individual “experimental subject”.
* (C) The research is conducted in compliance with all other applicable laws and regulations.
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| 7 | **Additional Criteria for research involving DoD-affiliated personnel** |
| [ ]  | Military personnel will not be paid for research conducted while on duty.[[10]](#endnote-9)  |
| [ ]  | If the research includes any risks to the subject’s fitness for duty (e.g., health, availability to perform job, data breach) the informed consent document must describe the risks and inform the subject that they should obtain command or component guidance before participating.  |
| [ ]  | The investigator must receive command or component approval to execute the research. |
| [ ]  | Military and civilian supervisors, officers, and other in the chain of command (i.e. superiors) will not influencing their subordinates to participate in research.  |
| [ ]  | Superiors will not be present at the time of recruitment and consent. |
| [ ]  | Where applicable, the consent documentation must include any potential risk of revocation of clearance, credentials, or other privileged access or duty.  |
| [ ]  | For research determined to be greater than minimal risk, where recruitment occurs in a group setting, the following criteria must be met:[ ]  The IRB must appoint an ombudsperson that is not a part of the research team and does not have a conflict of interest with the research.[ ]  The ombudsperson must be present during the recruitment to monitor that the recruitment and informed consent process explains the participation is voluntary, and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials. |
| [ ]  | For research that involves large scale genomic data, the following criteria must be met:[ ]  A disclosure that the genomic data may pose a risk to national security and the written materials must describe administrative, technical, and physical safeguards commensurate with risk including the secondary use or sharing of de-identified data or specimens.[ ]  A Certificate of Confidentiality from DHHS (Title 42,U.S.C. and Public Law 114-255) has been obtained.[ ]  The research will undergo a DoD component security review to ensure the adequacy of the proposed administrative, technical, and physical safeguards, including the secondary use or sharing of de-identified data or specimens. |
| [ ]   | Certificates of ConfidentialityAll studies involving large scale genomics data collected on/from DoD-affiliated personnel will apply an DHHS Certificate of Confidentiality.  See HRP 333: Certificate of Confidentiality for more information on Certificates of Confidentiality. |
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| 9 Additional Criteria for Department of Defense (DOD) Research Involving Classified Information[[11]](#endnote-10) (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 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 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.[[12]](#endnote-11) |
| [ ]  | Any IRB member who disagrees with a majority decision approving a project will be allowed to appeal the decision to the Secretary of Defense.[[13]](#endnote-12) |
| **10 UB does not conduct research involving chemical or biological agents.** |

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. [↑](#footnote-ref-1)
2. The IRB may rely on outside experts to provide an evaluation of the scientific merit. [↑](#endnote-ref-1)
3. 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. [↑](#endnote-ref-2)
4. 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. [↑](#endnote-ref-3)
5. 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. [↑](#endnote-ref-4)
6. 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. [↑](#endnote-ref-5)
7. When applicable, the superiors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session. [↑](#endnote-ref-6)
8. 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> [↑](#endnote-ref-7)
9. The ombudsman may also be the research monitor. [↑](#endnote-ref-8)
10. 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. [↑](#endnote-ref-9)
11. 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. [↑](#endnote-ref-10)
12. 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. [↑](#endnote-ref-11)
13. Include the appeal in the submission to the Secretary of Defense. [↑](#endnote-ref-12)