



Department of Defense Revisions to 32 CFR 219 and DoDI 3216.02

General Comments

This document lists the Standards and Elements where the US Department of Defense (DoD) requires additional protections.

DoD follows the Belmont Report, and the Common Rule, including Subparts B, C, D, and E, except where noted below. Organizations following the Common Rule must meet all Essential Requirements in the *Evaluation Instrument*, and Common Rule requirements described under DHHS regulations in the *Evaluation Instrument* (except where noted below).

DoD also follows FDA regulations, which are noted under FDA regulations in the *Evaluation Instrument*.

This document summarizes DoD requirements based on:

- DoD regulations adopting the revised Common Rule (32 CFR 219), including Subparts B, C, D, and E.
- DoDI 3216.02 (April 15, 2020), which incorporates other laws, regulations, and DoD Instructions, including but not limited to requirements under:
 - US Code Title 50, Section 1520a (Restrictions on use of human participants for testing of chemical or biological agents)
 - 10 USC 980 (Limitation on use of humans as “experimental subjects”)
 - 10 USC 139 (Inclusion of women and minorities in clinical research projects)
 - Executive Order 12333 of December 4, 1981 as amended, section 2.10 (Regarding classified research involving human participants).

The additional protections described below are focused on those most applicable to non-DoD organizations, such as universities engaged in research conducted or supported by the DoD. (Note: For DoD Components seeking accreditation, there are additional requirements not described here. “DoD components” include the Office of the Secretary of Defense (OSD), the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (DoDI 3216.02 section 1.1)).

Underlined text indicates new requirements or revisions to requirements in the *Evaluation Instrument*.

~~Strikethrough~~ text indicates previously included information in the *Evaluation Instrument* that are no longer required under the April 15, 2020 version of the DoDI 3216.02 or revised Common Rule (32 CFR 219).

Domain I: Organization

Standard I-1: The Organization has a systematic and comprehensive Human Research Protection Program with appropriate leadership.

Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection Program.

When following DoD requirements:

(a) Human participant research involving the testing of chemical or biological agents is prohibited, pursuant to Section 1520a of Title 50, United States Code (U.S.C.). Some exceptions for research for prophylactic, protective, or other peaceful purposes apply. Before any excepted testing of chemical or biological agents involving human participant research can begin, the DoD component seeking to conduct such research must obtain explicit written approval from the DoD Office for Human Research Protections (DOHRP). (DoDI 3216.02 section 1.2)

(i) Policies and procedures must specifically indicate whether the organization permits research involving chemical or biological agents under an exception, and if such research is allowed, describe who in the organization is responsible for obtaining approval and the process they go through.

(b) Written materials ensure “research involving a human being as an experimental subject” is conducted in accordance with 10 USC 980, as implemented by DoDI 3216.02, section 3.11.

(i) Research involving 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 “experimental subjects” is a subset of research involving human participants. This definition relates only to the application of Section 980 of Title 10, U.S.C.; it does not affect the application of 32 CFR 219.

(ii) Written materials must specifically indicate whether the organization conducts research involving experimental subjects.

(c) Classified research is defined in DoDI 3216.02 section 3.13.

(i) Policies and procedures must specifically indicate whether the organization allows the conduct of classified research, and must describe who in the organization is responsible for obtaining approval for such research and the process they go through.

Element I.1.E. The Organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.

~~(3) When following DoD requirements:~~

~~(a) Policies and procedures require initial and continuing research ethics education for all personnel who conduct, review, approve, oversee, support, or manage human participants research. (See requirement for DoD components to define training requirements in the component human research protection program management plan; DoDI 3216.02, section 3.2)~~

~~(i) There might be specific DoD educational requirements or certification required by different DoD components.~~

~~(ii) 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.~~

~~(b) Policies and procedures indicate how the IRB or EC staff, chair, and members; and researchers and research staff become aware of the specific requirements contained in DoD regulations and requirements and educated about these requirements when appropriate.~~

Element I.1.F. The Organization has and follows written policies and procedures for reviewing the scientific or scholarly validity of a proposed research study. Such procedures are coordinated with the ethics review process.

When following DoD requirements:

(a) If an IRB or EC at a non-DoD institution reviews DoD-supported research (DoDI 3216.02 sections 3.5 and 3.6):

(i) The IRB must consider the scientific merit of the research.

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

Standard I-2: The Organization ensures that the Human Research Protection Program has resources sufficient to protect the rights and welfare of research participants for the research activities that the Organization conducts or oversees.

(2) When following DoD requirements:

(a) Policies describe the process to confirm approval by the appropriate DoD component prior to research starting. DoD component-level administrative review (CLAR) must be conducted when (DoDI 3216.02 section 3.6):

(i) Human participants research is conducted in a foreign country, unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are US citizens.

(ii) The research requires a waiver of informed consent pursuant to 10 USC 980, Subsection (b).

(iii) The research is fetal research, as described in 42 USC 289g-289g-2.

(iv) 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)

(v) The research constitutes classified research involving human participants (DoDI 3216.02 section 3.13).

(vi) The research is required to be approved by the DOHRP (in addition to the COHRP) in accordance with DoDI 3216.02.

(b) Component review includes review of reliance agreements; see Standard I-9

~~(c) For DoD-supported non-exempt research involving human participants involving classified information reviewed by a non-DoD IRB, the involvement of classified information may be limited to information needed for IRB approval and oversight of the research; information needed to inform the human participants during the consent process; and information provided by human participants during the course of the research.~~

Standard I-3: The Organization's transnational research activities are consistent with the ethical principles set forth in its Human Research Protection Program and meet equivalent levels of participant protection as research conducted in the Organization's principal location while complying with local laws and taking into account cultural context.

(2) When following DoD requirements:

(a) Policies describe the process to confirm approval by the appropriate DoD component prior to research starting when human participants research is conducted in a foreign country, unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are US citizens. (See Standard I-2 for all component-level review requirements; DoDI 3216.02 section 3.6)

Standard I-5: The Organization measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The Organization also measures and improves, when necessary, the quality, effectiveness, and efficiency of the Human Research Protection Program.

Element I.5.D. The Organization has and follows written policies and procedures for addressing allegations and findings of non-compliance with Human Research Protection Program requirements. The Organization works with the Institutional Review Board or Ethics Committee, when appropriate, to ensure that participants are protected when non-compliance occurs. Such policies and procedures include reporting these actions, when appropriate.

When following DoD requirements:

~~(a) Any determinations of serious or continuing noncompliance of DoD-supported research must be promptly (within 30 days) reported to the DoD human research protection officer.~~

(a) Policies and procedures must describe 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) (DoDI 3216.02 section 3.6):

(i) 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.

(ii) Allegations of serious or continuing noncompliance related to research involving human participants that are substantiated by investigation, and subsequent actions taken based on the findings.

(iii) Substantiated allegations related to classified HSR must be reported immediately.

(Other reporting requirements are listed under Element II.2.G. and Element II.2.H.)

Standard I-9: The organization has written policies and procedures to ensure that, when sharing oversight of research with another organization the rights and welfare of research participants are protected.

(3) When serving as the reviewing IRB for a DoD-covered research study, policies and procedures or a written agreement must define the responsibilities of the DoD organization and non-DoD reviewing IRB, including but not limited to:

(a) DoD institutions collaborating with non-DoD institutions may rely on a collaborating non-DoD institution’s IRB if the following conditions are met (DoDI 3216.02 section 3.5):

(i) Each institution engaged in non-exempt human participant research must have a current federal assurance of compliance.

(ii) The non-DoD institution’s IRB is registered in accordance with Subpart E of 45 CFR 46.

(iii) The DoD institution reviews the protocol to ensure all applicable local and DoD requirements are addressed in the protocol.

(iv) The DoD institution, non-DoD institution, and the non-DoD institution’s IRB have a written agreement defining the responsibilities and authorities of each institution in complying with all legal requirements. This agreement must specify that the non-DoD IRB will apply the DoD requirements specified in DoDI 3216.02, including but not limited to non-DoD institutional responsibilities defined under DoDI 3216.02 section 3.6(b).

(v) If the research constitutes classified human participant research, the COHRP must approve the agreement to rely on the non-DoD institution's IRB.

Domain II: Institutional Review Board or Ethics Committee

Standard II-2: The IRB or EC systematically evaluates each research protocol or plan to ensure the protection of participants.

Element II.2.E. The IRB or EC has and follows written policies and procedures to conduct reviews by the convened IRB or EC.

1. Element II.2.E.1. – Initial review
2. Element II.2.E.2. – Continuing review
3. Element II.2.E.3. – Review of proposed modifications to previously approved research

(4) When following DoD requirements:

(a) Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD Information Management Control Officer (IMCO) after the research protocol is reviewed and approved by the IRB. When a survey crosses DoD components, additional review is required.

(i) Policies and procedures must specifically indicate whether the organization conducts research on DoD personnel, and if such research is allowed, describe who in the organization is responsible for obtaining approval and the process they go through.

(b) For DoD-supported research, the following must be promptly (AAHRPP defines "promptly" as within 30 days) reported to the COHRP. (DoDI 3216.02 section 3.6)

(i) When significant changes to the research protocol are approved by the IRB:

(A) Changes to key investigators or institutions.

(B) Decreased benefit or increased risk to participants in greater than minimal risk research.

(C) Addition of vulnerable populations as participants.

(D) Addition of DoD-affiliated personnel as participants.

(iii) Change of reviewing IRB.

(iv) When the organization 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.

(v) Any problems involving risks to participants or others, suspension or termination of IRB approval, or any serious or continuing noncompliance pertaining to DoD-supported human participant research.

(vi) The results of the IRB's continuing review, if required.

(vii) Change in status when a previously enrolled participant becomes pregnant, or when the researcher learns that a previously enrolled participant is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with 45 CFR 46, Subpart B.

(vii) Change in status when a previously enrolled participant becomes a prisoner, and the protocol was not reviewed and approved by the IRB in accordance with 32 CFR 219, Subpart C.

(viii) Closure of a DoD-supported study.

Element II.2.F. The IRB or EC has and follows written policies and procedures to conduct reviews by an expedited procedure, if such procedure is used.

Element II.2.F.1. – Initial review

Element II.2.F.2. – Continuing review

Element II.2.F.3. – Review of proposed modifications to previously approved research

When following DoD requirements:

(a) Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD Information Management Control Officer (IMCO) after the research protocol is reviewed and approved by the IRB. When a survey crosses DoD components, additional review is required.

(b) For DoD-supported research reviewed using the expedited procedure, organizations must follow the same reporting requirements described in Element II.2.E.

Element II.2.G. The IRB or EC has and follows written policies and procedures for addressing unanticipated problems involving risks to participants or others, and for reporting these actions, when appropriate.

When following DoD requirements:

The following must be promptly (AAHRPP defines “promptly” as within 30 days) reported to the COHRP (3216.02 section 3.6(b):

(a) Unanticipated problems involving risks to participants or others and any subsequent actions taken based on the findings. ~~for any DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD Office for Human Research Protections. DoD human research protection officer.~~

Element II.2.H. The IRB or EC has and follows written policies and procedures for suspending or terminating IRB or EC approval of research, if warranted, and for reporting these actions, when appropriate.

When following DoD requirements:

The following must be promptly (AAHRPP defines “promptly” as within 30 days) reported to the COHRP (3216.02 section 3.6(b):

- ~~(a) Suspensions or terminations of IRB approval. DoD-supported research must be promptly (no longer than within 30 5 days) reported to the DoD human research protection officer.~~

Element II.2.I. The IRB or EC has and follows policies and procedures for managing multisite research by defining the responsibilities of participating sites that are relevant to the protection of research participants, such as reporting of unanticipated problems or interim results.

(3) When following DoD requirements:

- (a) If conducting multi-site research, policies and procedures indicate that a formal agreement between organizations is required to specify the roles and responsibilities of each party. (See Standard I-9)

Standard II-3: The IRB or EC approves each research protocol or plan according to criteria based on applicable laws, regulations, codes, and guidance.

Element II.3.A. The IRB or EC has and follows written policies and procedures for identifying and analyzing risks and identifying measures to minimize such risks. The analysis of risk includes a determination that the risks to participants are reasonable in relation to the potential benefits to participants and to society.

(2) When following DoD requirements:

- ~~(a) The definition of the minimal risk based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” must not be interpreted to include the inherent risks certain categories of human participants face in their everyday life. For example, the risks imposed in research involving human participants focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).~~

(a) The definition of minimal risk in 32 CFR 219 does not include the inherent occupational risks that certain participants face in their everyday life, such as those:

- (i) Encountered by Service members, law enforcement, or first responders while on duty.
- (ii) Resulting from or associated with high-risk behaviors or pursuits.

(iii) Experienced by individuals whose medical conditions involve frequent tests or constant pain.

Element II.3.B. The IRB or EC has and follows written policies and procedures for reviewing the plans for data and safety monitoring, when applicable, and determines that the data and safety monitoring plan provides adequate protection for participants.

When following the DoD requirements:

A research monitor is not required. Researchers may remove the requirement for a research monitor from existing open studies through a modification approved by an IRB. (Note: This is distinct from a data and safety monitoring plan, which an IRB or EC may still require.)

The IRB considers the appointment of a research monitor:

- ~~Required for research involving greater than minimal risk, although the IRB or EC or organizational official can require this for a portion of the research or studies involving no more than minimal risk, if appropriate.~~
- ~~The research monitor is appointed by name and shall be independent of the team conducting the research.~~
- ~~There may be more than one research monitor (e.g., if different skills or experience are needed.)~~
- ~~The monitor may be an ombudsman or a member of the data safety monitoring board. The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities.~~
- ~~The IRB or HRPP official shall communicate with research monitors to confirm their duties, authorities, and responsibilities.~~
- ~~The duties of the research monitor are determined on the basis of specific risks or concerns about the research, such as:~~

~~Perform oversight functions (e.g., observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to participants or others, oversee data matching, data collection, and analysis).~~

~~Discuss the research protocol with researchers, interview human participants, and consult with others outside of the study.~~

~~Report observations and findings to the IRB or a designated official.~~

- ~~The research monitor has the authority to:~~

~~Stop a research study in progress.~~

~~Remove individuals from study.~~

~~Take any steps to protect the safety and well-being of participants until the IRB can assess.~~

Element II.3.C. The IRB or EC has and follows written policies and procedures to evaluate the equitable selection of participants.

When following DoD requirements:

- (a) DoD-affiliated personnel, U.S. military personnel, superiors of service members (e.g., unit officers, senior NCOs, and equivalent civilians), military and civilian supervisors, officers, and others in the chain of command (DoDI 3216.02 Section 3.9(f)):
 - ~~(i) Are prohibited from influencing their subordinates to participate in research involving human participants. not permitted to influence the decision of their subordinates.~~
 - ~~(ii) Must May not be present at the time of recruitment at any human participant recruitment sessions or during the consent process for DoD-affiliated personnel.~~
 - ~~(iii) May participate in separate human participant research recruitment sessions. Have a separate opportunity to participate.~~

~~When recruitment involves a percentage of a unit, an independent ombudsman must be present.~~
- (b) For greater than minimal risk research involving DoD-personnel, when recruitment and consent occurs in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:
 - (i) Must not have a conflict of interest with the research or be a part of the research team.
 - (ii) Must be present during human participant recruitment, monitoring that the recruitment and informed consent 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.
 - (iii) Should be available to address DoD-affiliated personnel's concerns about participation.
- (b) When research involves U.S. military personnel, limitations on dual compensation (DoDI section 3.9):
 - (i) Prohibit an individual from receiving pay of compensation for research during duty hours.
 - (ii) U.S. military personnel may be compensated for research if the participant is involved in the research when not on duty, provided payment does not conflict with prohibitions about dual compensation or other prohibitions in federal law.
 - (iii) Federal employees while on duty and non-federal persons may be compensated for blood draws for research up to \$50 for each blood draw.
 - (iv) Non-federal 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.

Element II.3.E. The IRB or EC has and follows written policies and procedures to evaluate proposed arrangements for maintaining the confidentiality of identifiable data, when appropriate, preliminary to the research, during the research, and after the conclusion of the research.

When following DoD requirements:

Additional confidentiality protections include (DoDI 3216.02 section 3.14):

(a) Data or information acquired by the DoD component under a pledge of confidentiality for exclusively statistical purposes must be used exclusively for statistical purposes and may not be disclosed in identifiable form for any other purpose, except with the informed consent of the respondent.

(b) All studies involving large scale genomic data collected on/from DoD-affiliated personnel will apply an DHHS Certificate of Confidentiality.

Element II.3.F. The IRB or EC has and follows written policies and procedures to evaluate the consent process and to require that the researcher appropriately document the consent process.

When following DoD requirements:

(a) Policies and procedures have the IRB or EC determine that the disclosure for research-related injury follow the requirements of the DoD component.

(Table II.3.F.1.): If the research involves DoD-affiliated personnel as participants, in addition to the basic and required consent disclosures, consent documents must include:

(i) 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.

(ii) If applicable, a statement of potential risks for the revocation of clearance, credentials, or other privileged access or duty.

(iii) A statement that the DoD or a DoD organization is funding the study.

(iv) A statement that representatives of the DoD are authorized to review research records.

(b) The IRB must determine that the disclosure includes that provisions for research-related injury follow the requirements of the DoD component.

(Table III.1.F.1.): For greater than minimal risk research, consent documents must include the disclosure that participants 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 participants' participation in the study to such time after the study has ended.

(d) Written materials must document how organizations will care for participants with research-related injuries, including injuries that are the direct result of activities performed by DoD-affiliated personnel in studies that are collaborative with a non-DoD institution.

(c) For greater than minimal risk research involving DoD-personnel, when recruitment and consent occur in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:

(i) Must not have a conflict of interest with the research or be a part of the research team.

(ii) Must be present during the HSR recruitment, monitoring that the recruitment and informed consent 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.

(iii) Should be available to address DoD-affiliated personnel's concerns about participation.

(D) 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 participant in advance, in accordance with 10 USC 980.

(i) If the participant is unable to provide informed consent and consent will be obtained in advance from the participant's legal representative, the research must be intended to benefit the individual participants.

Element II.3.G. The IRB or EC has and follows written policies and procedures for approving waivers or alterations of the consent process and waivers of consent documentation.

(5) When following DoD requirements:

(a) 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.

(i) 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 participant (i.e., the consent indicates that participation in the research is voluntary and the participant/representative is informed of research risks).

(ii) The Assistant Secretary for Defense for Research and Engineering 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.

(iii) Waivers of consent are prohibited for DoD classified research (Section 2.10 of Executive Order 12333)

~~(b) If the research participant does not meet the definition of "experimental subject" as defined in DODI 3216.02, policies and procedures allow the IRB or EC to waive the consent process.~~

Standard II-4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.

Element II.4.A. The IRB or EC has and follows written policies and procedures for determining the risks to prospective participants who are vulnerable to coercion or undue influence and ensuring that additional protections are provided as required by applicable laws, regulations, codes, and guidance.

~~(5)~~(3) When following DoD requirements, organizations must comply with all requirements in Subparts B, C, and D, with the qualifications below (32 CFR 219.111.(b)) and DoDI 3216.02):

(a) Research involving pregnant women, prisoners, and children are subject to the DHHS Subparts B, C, and D, except where modified by DoDI 3216.02. (DoDI 3216.02 section 3.9)

(b) For purposes of applying Subpart B, the phrase “biomedical knowledge” ~~shall be~~ is replaced with “generalizable knowledge.” (DoDI 3216.02 section 3.9 (b)):

(i) The applicability of Subpart B is limited to research involving pregnant women as participants in research that is greater than minimal risk and includes interventions or invasive procedures involving the woman or the fetus as participants, or fetuses or neonates as human participants.

(ii) Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g:

(A) 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:

(1) May enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

(2) 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.

(B) 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.

(c) For human participant research that would not otherwise be approved but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, written approval from the DOHRP must be obtained through the COHRP prior to research starting.

~~(e) Research involving prisoners cannot be reviewed by the expedited procedure.~~

~~(f) When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum. The prisoner representative may be a prisoner, an employee of the prison, or an individual not affiliated with the prison.~~

(d) In addition to the categories of permissible human participant research involving prisoners identified in DHHS regulations Subpart C, two additional categories are permissible (DoDI 3216.02 section 3.9 (c)):

(i) Epidemiological research is permitted under the following conditions:

(A) Where the sole purpose of the research is to describe the prevalence or incidence of a disease by identifying all cases, or study potential risk factor associations for a disease.

(B) The research presents no more than minimal risk.

(C) The research involves no more than inconvenience to the prisoner-participants.

(D) Prisoners are not a particular focus of the research.

(ii) Human participant research involving prisoners that would otherwise meet exemption criteria may be conducted, but must first be approved by an IRB and meet the requirements of Subpart C and DoDI 3216.02.

~~(h) If a participant becomes a prisoner, if the researcher asserts to the IRB that it is in the best interest of the prisoner participant to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner participant may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the organizational official and DoD Component office review the IRB's approval to change the research protocol. Otherwise, the IRB chair shall require that all research interactions and interventions with the prisoner participant (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol. The convened IRB, upon receipt of notification that a previously enrolled human participant has become a prisoner, shall promptly (no longer than 30 days) re-review the research protocol to ensure that the rights and wellbeing of the human participant, now a prisoner, are not in jeopardy. The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative. If the prisoner participant can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner participant's confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human participants from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner participant to continue to participate in the research. This approval is limited to the individual prisoner participant and does not allow recruitment of prisoners as participants.~~

(e) DoD organizations conducting research involving prisoners must demonstrate to the senior designated official that the IRB has fulfilled its duties in accordance with Subpart C.

(f) When a previously enrolled human participant becomes a prisoner, and the protocol has not been reviewed and approved by the IRB in accordance with Subpart C, the researcher must promptly notify the IRB.

(i) For DoD-conducted research, the human protections director must notify the COHRP.

(ii) For DoD-supported research, the non-DoD organization must notify the DoD human research protection official DOHRPO and other federal agencies.

(iii) The DOHRP must concur with the IRB before the participant can continue to participate while a prisoner.

~~(i) Research involving prisoners cannot be reviewed by the expedited procedure.~~

~~When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum.~~

~~In addition to allowable categories of research on prisoners in Subpart C, epidemiological research is also allowable when:~~

~~The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.~~

~~The research presents no more than minimal risk.~~

~~The research presents no more than an inconvenience to the participant.~~

~~If a participant becomes a prisoner, if the researcher asserts to the IRB that it is in the best interest of the prisoner participant to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner participant may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the organizational official and DoD Component office review the IRB's approval to change the research protocol. Otherwise, the IRB chair shall require that all research interactions and interventions with the prisoner participant (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol. The convened IRB, upon receipt of notification that a previously enrolled human participant has become a prisoner, shall promptly (no longer than 30 days) re-review the research protocol to ensure that the rights and wellbeing of the human participant, now a prisoner, are not in jeopardy. The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative. If the prisoner participant can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner participant's confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human participants from continuing as approved, the convened IRB may~~

~~approve a change in the study to allow this prisoner participant to continue to participate in the research. This approval is limited to the individual prisoner participant and does not allow recruitment of prisoners as participants.~~

(g) Research involving a detainee or a prisoner of war as a human participant is prohibited. (DoDI 3216.02 section 3.9 (g)):

(i) This prohibition does not apply to activities covered by investigational new drug or investigational device provisions of FDA regulations, when the purpose is for diagnosis or treatment of a medical condition in a patient.

(ii) Such treatment may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to FDA regulations, and only when the same product may be available to DoD-affiliated personnel consistent with established medical practices.

~~(i) Research involving a detainee as a human participant is prohibited.~~

~~This prohibition does not apply to research involving investigational drugs and devices when the same products would be offered to US military personnel in the same location for the same condition.~~

~~(i) The exemption for research involving survey or interview procedures or observation of public behavior does not apply to research with children, except for research involving observations of public behavior when the researcher(s) do not participate in the activities being observed.~~

~~(j) The exemption for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.~~

~~(k) Research involving prisoners of war is prohibited.~~

~~(l) The IRB or EC is aware of the definition of "prisoner of war" for the DoD component granting the addendum.~~

(h) Service members and DoD-affiliated personnel are considered to be vulnerable to coercion and undue influence by the DoD due to the nature of the command structure of the organization. Therefore, additional protections for DoD-affiliated personnel are required, as follows (DoDI 3216.02 section 3.9 (f)):

(i) If the research involves DoD-affiliated personnel as participants and if the research includes any risks to their fitness for duty (e.g., health, availability to perform job, data breach), the informed consent document must inform DoD-affiliated personnel about these risks and that they should seek command or component guidance before participating.

(ii) If the research involves DoD-affiliated personnel, the researcher must receive command or component approval to execute the research.

(iii) Military and civilian supervisors, officers, and others in the chain of command are prohibited from influencing their subordinates to participate in research.

(iv) Military and civilian supervisors, officers, and others in the chain of command must not be present at any participant recruitment sessions or during the consent process for DoD-affiliated personnel. Excluded supervisors or those in the chain of command may participate in separate recruitment sessions, if applicable.

(v) Service members and all Reserve component and National Guard members in a federal duty status are considered to be adults. If a Service member, Reserve component or National Guard member in federal duty status, student at a Service Academy, or trainee is under 18 years of age, the IRB must carefully consider the HSR recruitment process and the necessity of including such member as a human participant.

(vi) In order to approve research involving DoD-affiliated personnel, the IRB or component HRPO must determine whether the following requirements have been satisfied:

(A) The consent documentation must include, if applicable, potential risks for revocation of clearance, credentials, or other privileged access or duty.

(B) For research involving recruitment of DoD-affiliated personnel in research determined to be greater than minimal risk, and when recruitment occurs in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:

(I) Must not have a conflict of interest with the research or be a part of the research team.

(II) Must be present during the recruitment, monitoring that the recruitment and informed consent 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.

(III) Should be available to address DoD-affiliated personnel's concerns about participation

(vi) Compensation to DoD-affiliated personnel for participation in research while on duty is prohibited in accordance with 5 USC, with particular reference to Subparts G and H, with some exceptions for purposes consistent with 24 USC 30.

(i) Research involving large-scale genomic data from DoD-affiliated personnel is subject to additional requirements (DoDI 3216.02 section 3.10):

(i) The disclosure of DoD-affiliated personnel's genomic data may pose a risk to national security; accordingly, written materials must describe administrative, technical, and physical safeguards commensurate with risk, including the secondary use or sharing of de-identified data or specimens.

(ii) All research involving large-scale genomic data collected from DoD-affiliated personnel must have a certificate of confidentiality from DHHS (Title 42, U.S.C., and Public Law 114-255).

(iii) Research involving large-scale genomic data collected from DoD-affiliated personnel is subject to 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.

(j) DoD organizations must demonstrate to the senior designated official that the IRB has fulfilled its duties in accordance with DHHS Subpart D, 45 CFR 46. 407 and 21 CFR 50.54.

Element II.4.B. The IRB or EC has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question.

(5) When following DoD requirements:

(a) If consent is to be obtained from the legal representative of the experimental subject, the research must intend to benefit each participant enrolled in the study.

Element II.4.C. The IRB or EC has and follows written policies and procedures for making exceptions to consent requirements for planned emergency research and reviews such exceptions according to applicable laws, regulations, codes, and guidance.

(5) When following DoD requirements:

(a) When conducting emergency medicine research, policies and procedures describe the process to obtain approval from the DOHRP on behalf of the Secretary of Defense for a waiver of the advance informed consent provision of 10 USC 980.

Standard II-5: The IRB or EC maintains documentation of its activities.

Element II.5.A. The IRB or EC maintains a complete set of materials relevant to the review of the research protocol or plan for a period of time sufficient to comply with legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures.

When following DoD (DoD) requirements:

(a) Records maintained by non-DoD organizations that document compliance or noncompliance with DoD requirements shall be made accessible for inspection and copying by representatives of the DoD. ~~at reasonable times and in a reasonable manner as determined by the supporting DoD component.~~

Element II.5.B. The IRB or EC documents discussions and decisions relevant to a research protocol or plan in accordance with legal and regulatory requirements, Sponsor requirements, if any, and organizational policies and procedures.

(4) When following DoD requirements:

(a) Records maintained by non-DoD organizations that document compliance or noncompliance with DoD regulations must be made accessible for inspection and copying by representatives of the DoD. ~~at reasonable times and in a reasonable manner as determined by the supporting DoD component.~~

Domain III: Researcher and Research Staff

Standard III-1: In addition to following applicable laws and regulations, Researchers and Research Staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, Researchers and Research Staff have the protection of the rights and welfare of research participants as a primary concern.

Element III.1.E. Researchers and Research Staff recruit participants in a fair and equitable manner.

(7) When following DoD requirements:

(a) Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with Service-specific requirements.