**Instructions:** The purpose of this form is to determine if human research sponsored or funded by the Department of Defense (DoD) meets the criteria outlined in the [**DoD Instruction 3216.02**](https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf) and federal regulations ([**32 CFR 219**](https://www.ecfr.gov/current/title-32/subtitle-A/chapter-I/subchapter-M/part-219?toc=1)). All human research conducted or supported by DoD must meet the standards outlined in the checklist below.

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| |  |  | | --- | --- | | **Basic Information** | | | **Title of Study:** |  | | **Short Title:** |  | | **Principal Investigator Name:** |  | | |
| Criteria for Department of Defense (DOD) Research  (All must be checked “Yes” or “N/A”) | |
| Yes  No | The research does NOT involve prisoners of war as subjects. This includes any person captured, detained, held, or otherwise under the control of DoD personnel (military and civilian, or contractor employee). Such persons include: enemy prisoners, civilian internees, retained persons, and lawful and unlawful enemy combatants. Such persons do not include DoD personnel being held for law enforcement purposes.   1. The prohibition does not apply to activities covered by investigational new drug or investigational device provisions of [CFR Title 21](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm) when the purpose is for diagnosis or treatment of a medical condition in a patient. 2. Such treatment may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to [CFR Title 21](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm) and only when the same product may be available to DoD-affiliated personnel consistent with established medical practices. 3. Epidemiological research that meets the waiver criteria in accordance with [Pages 36929-36931 of Volume 68, Federal Register](https://www.federalregister.gov/documents/2003/06/20/03-15580/waiver-of-the-applicability-of-certain-provisions-of-department-of-health-and-human-services), may be approved in accordance with the applicable requirements of [45 CFR 46 Subpart C](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-C), the [DoD Instruction 3216.02](https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf), and other applicable requirements. 4. Human Subject Research (HSR) that would otherwise meet exemption criteria may be conducted but must first be approved by an IRB and must meet the requirements in [45 CFR 46 Subpart C](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-C), the [DoD Instruction 3216.02](https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf), and other applicable requirements. |
| Yes  No  N/A | Informed Consent Considerations:   1. If the research involves interventions or interactions with subjects, the research does not involve a waiver of consent or parental permission unless a waiver is obtained from the Secretary of Defense. **(“N/A” if no interactions or interventions with subjects)** 2. For research governed by [10 USC 980](https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title10-section980&num=0&edition=prelim) that involves no more than minimal risk, as defined by [32 CFR 219](https://www.ecfr.gov/current/title-32/subtitle-A/chapter-I/subchapter-M/part-219?toc=1), an IRB may alter or waive other required elements of informed consent pursuant to [32 CFR 219](https://www.ecfr.gov/current/title-32/subtitle-A/chapter-I/subchapter-M/part-219?toc=1), so long as it still preserves informed consent of the subject (i.e., the consent indicates the subject’s participation in the research is completely 3. The advance informed consent requirement pursuant to [10 USC 980](https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title10-section980&num=0&edition=prelim), may be waived by the DoD Office for Human Research Protections or its delegate, if the following conditions are met: 4. The research is to advance the development of a medical product necessary to the DoD. 5. The research may directly benefit the individual experimental subject. 6. The research is conducted in compliance with all other applicable laws and regulations. |
| Yes No | The project utilizes a single institutional review board (IRB) in accordance with [32 CFR 219.114](https://www.ecfr.gov/current/title-32/section-219.114). |
| Yes  No | The proposed protocol demonstrates sound scientific merit and feasibility of study completion and realistic. |
| Yes  No  N/A | If collecting Large Scale Genomic Data (LSGD), a Certificate of Confidentiality (COC) has been obtained. The informed consent contains the COC language. |
| Yes  No  N/A | If the HSR involves DoD-affiliated personnel as subjects and if the HSR 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. |
| Yes  No  N/A | The consent documentation must include, if applicable, potential risks for the revocation of clearance, credentials, or other privileged access or duty. |
| Yes  No | Compensation to DoD-affiliated personnel for participation in research while on duty is prohibited in accordance with [Title 5, USC](https://www.ecfr.gov/current/title-5). |
| Yes  No | All research personnel have completed the DoD Component human subject protection training. |
| Yes  No  N/A | For research involving more than minimal risk to subjects: **(“N/A” if no more than minimal risk)**  Reported observations and findings must be submitted to the IRB or designated official.  The IRB or HSPP 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:   1. 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). 2. Discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study. |
| Yes  No  N/A | For research involving more than minimal risk to subjects AND involving military personnel: **(“N/A” if no more than minimal risk OR if not involving military personnel)**  Unit officers and noncommissioned officers will not influence the decisions of their subordinates to participate or not to participate as research subjects.  Unit officers and senior non-commissioned officers in the chain of command will not be present at the time of research subject solicitation and consent during any research recruitment sessions in which members of units under their command are afforded the opportunity to participate as research subjects.  When applicable, officers and non-commissioned officers so excluded will be afforded the opportunity to participate as research subjects in a separate recruitment session.  During recruitment briefings to a unit where a percentage of the unit is being recruited to participate as a group, an ombudsman not connected in any way with the proposed research or the unit will be present to monitor that the voluntary nature of individual subjects is adequately stressed and that the information provided about the research is adequate and accurate. |
| Yes  No  N/A | The disclosure regarding provisions for research-related injury follows the requirements of the DoD component: **(“N/A” if no requirements of the Department of Defense component)**   1. All HSR that is determined to be greater than minimal risk must meet the requirement of [32 CFR 219.116](https://www.ecfr.gov/current/title-32/section-219.116), to provide subjects with an explanation as to whether any compensation and any medical treatments are available for research–related injuries. 2. Explanations must include a statement that subjects may, for the duration of the study, be eligible for health care services for research-related injuries at a military treatment facility, in accordance with [32 CFR 108](https://www.ecfr.gov/current/title-32/subtitle-A/chapter-I/subchapter-D/part-108). This eligibility for health care services extends beyond subjects’ participation in the study to such time after the study has ended, in accordance with [32 CFR 219.108](https://www.ecfr.gov/current/title-32/subtitle-A/chapter-I/subchapter-M/part-219/section-219.108). 3. Subjects injured in DoD-conducted research may obtain care for such injuries at a DoD medical treatment facility on a space-available basis during the pendency of the research study in accordance with [DoDI 6025.23](https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/602523p.pdf). |