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| The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314) when HSR is funded or supported by the Department of Defense (DoD). This checklist or equivalent must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)   * For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist or equivalent to document determinations required by the regulations and guidance. The Designated Reviewer attaches this checklist or equivalent to CHECKLIST: Non-Committee Review (HRP-402) or equivalent. The IRB Administration retains this checklist or equivalent in the protocol file.   For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist or equivalent made on the previous review have changed, the convened IRB completes this checklist or equivalent to document determinations required by the regulations and guidance and the IRB Administration retains this checklist or equivalent in the protocol file. | |
| Additional Criteria for Department of Defense (DOD) Research *(Check if “Yes” or “N/A”. All boxes in column on left must be checked)* | |
|  | If the research involves more than one site conducting the same protocol, only one IRB is overseeing the research.  N/A. This study does not involve more than one research site conducting the same protocol. |
|  | All researchers at non-DOD institutions are covered by their own institution’s FWA or by another institution’s FWA assurance through an Individual Investigator Agreement. |
|  | The Institution is submitting the following to HRPO  Documentation that the IRB has approved the DoD-supported HSR, including scientific merit, amendments, and additional reviews.  Documentation of key investigators’ human research protection training.  IRB-approved protocol documents.  Current FWA and IRB registration numbers. |
|  | The approval letter includes the following statements:  The IRB determined the HSR has scientific merit  The Investigator must notify HRPO of the following:   * IRB-approved changes to key investigators * Changes to institutions * Decreases in benefit to subjects * Increases in risk * The addition of vulnerable populations, or DoD-affiliated personnel as subjects * Transfer of HSR oversight to a different IRB * Notification by any federal body or foreign government that the DOD-supported HSR is under investigation * When a subject becomes pregnant in a study that was not approved under 45 CFR 46 Subpart B * When a subject becomes a prisoner in a study that was not reviewed under 45 CFR 46 Subpart C * Study closure |
|  | The investigator and research staff are aware of the specific DOD requirements and have been educated about these requirements. |
|  | The review has considered and documented the scientific merit of the research.[[1]](#endnote-2) |
|  | When determining the level of risk, the IRB did not consider include the inherent occupational risks that certain subjects face in their everyday life, such as those:  (1) Encountered by Service members, law enforcement, or first responders while on duty.  (2) Resulting from or associated with high-risk behaviors or pursuits.  (3) Experienced by individuals whose medical conditions involve frequent tests or constant pain. |
|  | This research involves human beings involved in an intervention or interaction done primarily for the research purpose of obtaining data about the effect of the intervention or interaction.  Yes  No  ***If yes is checked, one of the following must be checked:***  Full informed consent is not waived for these subjects (see below).  The research involves only minimal risk and the IRB waived one or more element of consent but required the consent process to include a statement that participation is voluntary and to describe the risks of participation.  If the research involves cognitively impaired subjects, the research presents a prospect of direct benefit the subject.  N/A |
|  | The research does **NOT** involve prisoners of war or detainees as subjects.[[2]](#endnote-3) |
|  | If children are involved, the research complies with 45 CFR 46 Subpart D. Service members and all Reserve Component and National Guard members in a federal duty status are considered to be adults.  N/A. The research does not involve children |
|  | If pregnant women are involved in the research, one of the following must be checked:  The research does not involve greater than minimal risk and pregnant women, fetuses, or neonates and includes interventions or invasive procedures  The research complies with 45 CFR 46 Subpart B except the phrase “biomedical knowledge is replaced with “generalizable knowledge.”  Not applicable. The research does not involve pregnant women. |
|  | If the research involves prisoners as human subjects, the following must be checked:  A convened IRB must review the research (no expedited review)  The research complies with 45 CFR 46 Subpart C except the following two categories of research are permissible (a) Epidemiological research that meets the waiver criteria (See Federal Register Volume 68 pages 36929-36931 of Volume 68, Federal Register; or (b) The IRB approved HSR meets one or more exemption criteria and the IRB determined the research meets the requirements of 45 CFR 46 Subpart C  N/A prisoners are not included as subjects in this research |
|  | If the research is conducted by the DOD and involves greater than minimal risk, the consent form states that subjects may obtain treatment for research-related injuries at a military treatment facility until the study ends.  N/A the research is no more than minimal risk  N/A The research is not DOD conducted |
|  | 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. |
|  | Research involving fetal tissue must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g[[3]](#endnote-4). |
| **Additional Criteria for HSR involving DoD-affiliated personnel *(All boxes on left must be checked)*** | |
|  | Military personnel will not be paid for research conducted while on duty.[[4]](#endnote-5) |
|  | Military personnel will not be paid from federal funds for research conducted while off duty. |
|  | Research Involving DoD-affiliated personnel as subjects: ***This section has two parts:***  ***Part 1 - At least one of the following must checked:***  The consent form describes any risks to the subjects’ fitness for duty (e.g. health, availability to perform job, data breach) and the subject is advised that they should obtain command or Component guidance before participating  N/A The research involves only minimal risk  N/A The research does not involve DOD-affiliated personnel as subjects  ***and***  ***Part 2 - At least one of the following must checked:***  The consent form includes a description of the potential risks for the revocation of clearance, credentials, or other privileged access or duty.  N/A The research does not present any potential risk to a clearance, credentials or other privileged access or duty  N/A The research does not involve DOD-affiliated personnel as subjects |
|  | Research involving greater than minimal risk and recruits DoD-affiliated personnel in a group setting  ***If the last box isn’t checked, the first three boxes must be checked***  The IRB appointed an ombudsperson who does not have a COI with the research and is not part of the research team.  The ombudsperson will (a) be present and monitor recruitment and the informed consent process to ensure consent the activities are consistent with IRB-approved procedures and materials.  The ombudsperson will be available to address DoD-affiliated personnel’s concerns about participation.  N/A the research does not involve greater than minimal risk or does not recruit DOD-affiliated personnel in a group setting |
|  | Research using large scale genomic data  ***At least one of the following must be checked:***  The HSR does not involve collection, sharing or analysis of large-scale genomic data  ***If the above is checked, the following box must be checked:***  The HSR protocol or other document includes administrative, technical, and physical safeguards commensurate with the risk.  ***One of the following must be checked***:  The HSR involves collection, sharing or analysis of large-scale genomic data from DoD-affiliated personnel and adheres to 42 U.S.C and Public Law 114-255, has or will undergo a DoD Component security review, and has or will receive DOHRP approval.  The HSR does not involve collection, sharing or analysis of large-scale genomic data from DoD affiliated personnel |
|  | 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.[[5]](#endnote-6) |
|  | If the research involves a survey performed on DOD personnel, DOD approval will be obtained before the research commences. |
|  | 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.  Where differences in applicable standards exist, the standard that is most protective of human subjects will be applied.  An ethics review by the host country, or local IRB with host country representation, will take place. |
|  | If the research is not conducted at a US site or at a DOD facility outside of the US, the Lead PI has provided written notification of the applicable HSR to the commands where the HSR is to be conducted or supported in their area of responsibility before the HSR proceeds.  N/A. Research is conducted within US or at a DOD facility outside of the US. |
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| Additional Criteria for Department of Defense (DOD) Research Involving Classified Information[[6]](#endnote-7). (*All boxes on left must be checked)* | |
|  | The convened IRB approved the research. (Use of an expedited review procedure is prohibited.) |
|  | The IRB has determined that potential subjects need access to classified information to make a valid, informed consent decision. |
|  | The IRB has consulted with an expert on classified information. |
|  | The research does not involve a waiver of informed consent. |
|  | The informed consent includes a statement that representatives of the DoD are authorized to review research records. |
|  | The informed consent process identifies DOD as the supporting institution of the research, unless the research involves no more than minimal risk or the Secretary of Defense has granted an exception. |
|  | The informed consent includes a statement that the DoD or a DoD organization is funding the study. |
|  | The informed consent process includes a statement that the research is classified and an explanation of the impact of the classification. |
|  | Disclosure or use of classified information complies with the federal requirements for access to and protection of classified information. |
|  | Secretary of Defense approval will be obtained.[[7]](#endnote-8) |
|  | Any IRB member who disagrees with a majority decision approving a project will be allowed to appeal the decision to the Secretary of Defense.[[8]](#endnote-9) |

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