|  |  |
| --- | --- |
| **ID:** | Click or tap here to enter text formatted as Submission Number – PI Last Name. |
| **Notes:** | Click or tap here to enter text. |

Can research conducted or supported by DOD be approved?[[1]](#endnote-2),[[2]](#endnote-3)

|  |  |  |
| --- | --- | --- |
| Key | If the research is exempt, the criteria for all applicable yellow highlighted categories must be met. | If the research is non-exempt, the following General Criteria and all criteria for applicable categories (including yellow highlighted) must be met. |

|  |
| --- |
| 1. General Criteria (Check if **“Yes”**. All must be checked.)
 |
| [ ]  | * 1. The IRB has considered the scientific merit of the research.[[3]](#endnote-4)
 |
| 1. Researchers That Involves Any of the Below Circumstances Must Receive Approval by the Appropriate DoD Component Prior to Research Starting via DoD Component-Level Administrative Review (CLAR): (Check if **“Yes”**. If any checked, researchers must include an attestation that this review will occur). **N/A** [ ]
 |
| [ ]  | * 1. 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.
 |
| [ ]  | * 1. The involvement of DoD personnel in the conduct of the research is secondary to that of the non-DoD institution.
 |
| [ ]  | * 1. The research requires a waiver of informed consent pursuant to 10 USC 980, Subsection (b).
 |
| [ ]  | * 1. The research is fetal research, as described in 42 USC 289g-289g-2.
 |
| [ ]  | * 1. 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.
 |
| [ ]  | * 1. The research is required to be approved by the DOHRP (in addition to the COHRP) in accordance with DoDI 3216.02.
 |
| [ ]  | * 1. Component review includes review of reliance agreements.
 |
| 1. Research That Involves Informed Consent (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. The consent document states that the DOD or a DOD organization is funding the study.
 |
| [ ]  | * 1. The consent document states that representatives of the DOD are authorized to review research records.
 |
| [ ]  | * 1. The disclosure for research-related injury follows the requirements of the DOD component.
 |
| 1. Multi-Site Research (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. There is a formal agreement between organizations to specify the roles and responsibilities of each party.
 |
| [ ]  | * 1. If Temple University (non-DoD institution) will serve as the IRB of Record for a DoD institution, the following considerations apply. (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  | [ ]  | * + 1. Each institution engaged in non-exempt human subjects research has a current federal assurance of compliance.
 |
|  | [ ]  | * + 1. The non-DoD institution’s IRB is registered in accordance with Subpart E of 45 CFR 46.
 |
|  | [ ]  | * + 1. The DoD institution reviews the protocol to ensure all applicable local and DoD requirements are addressed in the protocol.
 |
|  | [ ]  | * + 1. The reliance agreement must specify the responsibilities and authorities of the DoD institution, non-DoD institution, and non-DoD institution’s IRB in complying with all legal requirements. It must also state 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).
 |
|  | [ ]  | * + 1. The research does not constitute classified human subjects research.[[4]](#endnote-5),[[5]](#endnote-6) If the research constitutes classified human subjects research, contact the [HRPP Administrator].
 |
| 1. Research That Involves an Alteration of Consent for "Experimental Subjects"[[6]](#endnote-7) and is <Minimal Risk> (Check if “Yes”. All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. Informed consent must be obtained from the participant or LAR in advance, in accordance with 10 USC 980. The IRB may waive or alter some elements of informed consent for non-exempt, <Minimal Risk>[[7]](#endnote-8) research involving human beings as experimental subjects, so long as it preserves the informed consent of the participant or LAR (i.e., the consent indicates that participation in the research is voluntary and the participant/representative is informed of research risks).
 |
| 1. Research That Involves a Waiver of Consent for "Experimental Subjects"6 (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. A waiver will be obtained from the DoD Office for Human Research Protections (DOHRP).[[8]](#endnote-9)
 |
| 1. Research That Involves LAR Permission for "Experimental Subjects"6(Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. The research holds out the prospect of direct benefit to the individual subject.[[9]](#endnote-10)
 |
| 1. Research That Involves Pregnant Women, <Fetuses>, or Neonates as Subjects (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. One of the following is true **(Check box that is true):**
 |
|  | [ ]  | * + 1. The research does not involve interventions or invasive procedures with more than <Minimal Risk>7 to subjects
 |
|  | [ ]  | * + 1. The research meets "CHECKLIST: Pregnant Women (HRP-305)"
 |
|  | [ ]  | * + 1. The research would not otherwise be approved as above, but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, and written approval from the DOHRP will be obtained through the COHPR prior to research starting.
 |
| 1. Research That Involves <Prisoners> as Subjects (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. The research meets the requirements of "CHECKLIST: Prisoners (HRP-308)"
 |
| [ ]  | * 1. The research does not involve prisoners of war or detainees as subjects[[10]](#endnote-11)
 |
| 1. Research That Involves <Children> as Subjects[[11]](#endnote-12) (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. The research meets "CHECKLIST: Children (HRP-310)"
 |
| 1. Research That Involves Fetal Tissue (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. The research complies with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g (Check if **“Yes”.** All must be checked.)
 |
|  | [ ]  | * + 1. 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 where one of the following is true: **(Check box that is true) N/A** [ ]
 |
|  |  | [ ]  | * + - 1. May enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability.
 |
|  |  | [ ]  | * + - 1. 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.
 |
|  | [ ]  | * + 1. 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.
 |
| 1. Research That Involves a Waiver of Consent for Planned Emergency Research (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. A waiver of the advance informed consent provision of 10USC 980 has been obtained from the DoD Office for Human Research Protections (DOHRP) on behalf of the Secretary of Defense.
 |
| 1. Research That Involves DoD-Affiliated Personnel[[12]](#endnote-13) as Subjects (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. The researcher must receive command or component approval to execute research involving DoD-affiliated personnel.
 |
| [ ]  | * 1. Superiors of DoD-affiliated personnel will not influence the decisions of their subordinates to take part in research.
 |
| [ ]  | * 1. Superiors of DoD-affiliated personnel in the chain of command will not be present at any recruitment sessions or during the consent process for DoD-affiliated personnel.[[13]](#endnote-14)
 |
| [ ]  | * 1. DoD-affiliated personnel will not receive payment for research conducted during duty hours.[[14]](#endnote-15)
 |
| [ ]  | * 1. If the research includes any risks to DoD-affiliated personnels’ 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.
 |
| [ ]  | * 1. The consent must include, if applicable, potential risks for the revocation of clearance, credentials, or other privileged access or duty.
 |
| [ ]  | * 1. 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 subject.
 |
| [ ]  | * 1. One of the following is true **(Check box that is true)**:
 |
|  | [ ]  | * + 1. The research does not involve non-exempt surveys administered to DoD personnel.
 |
|  | [ ]  | * + 1. The investigator will obtain approval of non-exempt surveys administered to DoD personnel from the DoD Information Management Control Officer (IMCO) following approval by the IRB. When a survey crosses DoD components, additional review is required.
 |
| [ ]  | * 1. Research That Involves Recruitment and/or Consent in a Group Setting and Involves Greater than <Minimal Risk>7 to Subjects (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  | [ ]  | * + 1. The IRB has appointed an ombudsperson, and the ombudsperson fits the below criteria (Check if **“Yes”.** All must be checked.) **N/A** [ ] :
 |
|  |  | [ ]  | * + - 1. Must not have a conflict of interest with the research or be a part of the research team.
 |
|  |  | [ ]  | * + - 1. Must be present during human subject 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.
 |
|  |  | [ ]  | * + - 1. Should be available to address DoD-affiliated personnel’s concerns about participation.
 |
| 1. Research Involving Large-Scale Genomic Data from/on DoD-Affiliated Personnel (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. The research must have and apply an HHS Certificate of Confidentiality.
 |
| [ ]  | * 1. 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.
 |
| [ ]  | * 1. The research 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.
 |
| 1. Research that Involves Data or Information Acquired by the DoD Component Under a Pledge of Confidentiality for Exclusively Statistical Purposes (Check if **“Yes”**. All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. 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.
 |
| 1. Classified Research4,5 regulated by the DoD is currently prohibited. If the proposed research constitutes classified human subjects research, contact the [HRPP Administrator].
 |

**Footnotes**

1. . [DoD Instruction 3216.02](https://www.esd.whs.mil/portals/54/documents/dd/issuances/dodi/321602p.pdf) Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research. [↑](#endnote-ref-2)
2. . In this worksheet, "research" means <Research as Defined by HHS> involving <Human Subjects as Defined by HHS>, and "subject" means <Human Subject as Defined by HHS>. [↑](#endnote-ref-3)
3. . The IRB may rely on outside experts to provide an evaluation of the scientific merit. [↑](#endnote-ref-4)
4. . Pursuant to Parts 22, 37, and 219 of Title 32, CFR, and Sections 2.101 and 252.235-7004 of Title 48, CFR, and Executive Order 13526, DoD-conducted or DoD-supported HSR is considered classified HSR when:

Classified information is required for IRB review and oversight of the research.

Classified information must be provided to human subjects, or their guardians, during the HSR recruitment or informed consent process in order to achieve fully effective legal consent.

Classified information is provided to, or by, research subjects. [↑](#endnote-ref-5)
5. . DoD-conducted or –supported HSR is not considered classified HSR:

If the HSR is a part of a classified program, but the research itself is not classified; if the information required in the research protocol is not classified; if the information needed by the IRB is not classified; or if the information required by the human subject is not classified. For the purposes of the annual report for classified research, unclassified HSR that falls into the criteria listed in this paragraph should be included in the report.

HSR that requires subjects to hold a clearance as a means of creating ease of entry or access to controlled spaces where the research will occur does not constitute classified HSR unless one of the conditions described in DOD INSTRUCTION 3216.02 Sections 3.13.b.(1) or (3) of also exist.

If the research constitutes an authorized operational activity, then it is not HSR. [↑](#endnote-ref-6)
6. . "Experimental Subject" means a living individual involved in an activity where, for research purposes, there is an <Intervention> or <Interaction> with that individual for the primary purpose of obtaining data regarding the effect of the <Intervention> or <Interaction>. "Experimental Subject" is a subset of <Human Subjects as defined by HHS>. 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. [↑](#endnote-ref-7)
7. . 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: (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. [↑](#endnote-ref-8)
8. . The DoD Office for Human Research Protections (DOHRP) may waive the requirements for prospective consent when all of the following 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. [↑](#endnote-ref-9)
9. . The determination that research is intended to be beneficial to the individual <Experimental Subject as Defined by DOD> must be made by an IRB. [↑](#endnote-ref-10)
10. . 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. 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. [↑](#endnote-ref-11)
11. . For purposes of legal capacity to participate in DoD-conducted or -supported research involving human subjects, all active duty Service members and all Reserve Component members in a Federal duty status are adults. The participation of such members is not subject to requirements of 45 CFR §46 Subpart D. [↑](#endnote-ref-12)
12. . [DoD Instruction 3216.02](https://www.esd.whs.mil/portals/54/documents/dd/issuances/dodi/321602p.pdf) defines “DoD-affiliated personnel” as “Service members, Reserve Service members, National Guard members, DoD civilians, and DoD contractors.” [↑](#endnote-ref-13)
13. . Superiors may have the opportunity to participate as human subjects in a separate recruitment session. [↑](#endnote-ref-14)
14. . An individual may be compensated for research involved in the research when not on duty. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw for purposes consistent with Section 30 of Title 24, U.S.C.. 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-15)