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| **DoDI 3216.02 Requirements** | **DoDI Requirement Met in CMP/Policies** |
| (1) Include or reference DoD Component policies to implement this issuance and  identify the responsible DoD Component office(s) for actions identified in this issuance. |  |
| (2) Identify the SDO with the authority and responsibility for implementing the CMP. |  |
| 1. Be consistent with DOHRP guidance and include or reference DoD Component policies and procedures, if applicable, that:    1. Establish authority for, and include or reference policies under which, the COHRP will issue, limit, or revoke DoD assurances upon assessment of institutions’ HRPPs.   **Policy on Assurances** |  |
| (b) Describe the DoD Component’s program or provisions for exercising authorities delegated from the DOHRP to the SDO. **Request Delegations or Waiver Items listed at the end of this checklist.** |  |
| (c) Describe, consistent with DOHRP guidance, the DoD Component’s implementation of security review of research involving LSGD collected from DoD- affiliated personnel and procedures to obtain SDO and DOHRP approval.  **LSGD Policy**  a. DoD-conducted or DoD-supported research involving LSGD collected on DoD-affiliated personnel, or for which research the DoD provides assistance, is subject to additional requirements in this issuance.  b. The disclosure of DoD-affiliated personnel’s genomic data may pose a risk to national security; accordingly, such research requires administrative, technical, and physical safeguards commensurate with risk, including the secondary use or sharing of de-identified data or specimens.  c. All research involving LSGD collected from DoD-affiliated personnel will apply an HHS CoC pursuant to Title 42, U.S.C., and Public Law 114-255.  d. Research involving LSGD collected from DoD-affiliated personnel is subject to DoD Component security review to ensure the adequacy of the proposed administrative, technical, and physical safeguards, |  |
| (d) Establish DoD Component and institutional requirements for human subject protection training. |  |
| (e) Establish procedures for certification in accordance with Part 219 of Title 32, CFR. |  |
| (f) Establish policy for designating human protections directors (HPDs), human research protection official(s) (HRPOs) and exemption determination officials (EDOs) to include specifying qualifications, training, and responsibilities. |  |
| (g) Establish policy and institutional requirements for managing allegations of, and reporting noncompliance with, federal regulations, State and local laws, Native American or Alaskan native tribal laws, foreign laws, and DoD issuances and policies. |  |
| (h) Establish DoD Component and institutional responsibilities for required reporting to the DOHRP, including reports pursuant to Title 32, CFR.  **Can include DOHRP Reporting Document** |  |
| (i) Establish policy and institutional requirements for managing conflicts of interest, including financial and non-financial interest conflicts, personal considerations, or perceptions of a possible conflict. |  |
| (j) Establish policy for the maintenance of HSR records, including records and workflows maintained in electronic form, required by governing regulations and this issuance. |  |
| (k) Establish policy in accordance with DoDI 6025.23 for addressing subjects’ research- related injuries in DoD-conducted research. |  |
| (l) Establish policy and institutional requirements for HRPO review of DoD- supported HSR conducted by non-DoD institutions. **See HRPO Requirements.** |  |

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| **CLAR 3.5.b. and 3.6.a.**  (1) The DoD Component must conduct an administrative review (also known as a component-level administrative review (CLAR)) of all non-exempt HSR when any of the following conditions occur:  (a) HSR is conducted in a foreign country, unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are U.S. citizens.  (b) The research requires a waiver of informed consent pursuant to Subsection (b) of Section 980 of Title 10, U.S.C.  (c) The research is fetal research, as described in Sections 289g–289g-2 of Title 42, U.S.C.  (d) LSGD is collected from DoD-affiliated personnel.  (e) The research constitutes classified HSR as defined by this issuance.  (f) Research is required to be approved by the DOHRP.  (2) DoD administrative and DoD Component security reviews must be conducted before research involving LSGD collected from DoD-affiliated personnel may begin.  (3) The DoD Component may, with DOHRP approval, delegate Component review and oversight of Sections 3.5.b.(1)(a) - (f) to a DoD institution. |  |
| A DoD Component may, in a written arrangement approved by the DOHRP, rely on another DoD Component to implement elements of the relying DoD Component’s CMP, except for designating the relying DoD Component’s SDO. The DoD Component relying on another DoD Component to implement elements of its CMP must specify the existence and extent of any such reliance in its CMP. |  |
| **Policy on DoD-Affiliated Personnel**  (1) 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 (ICD) must inform DoD-affiliated personnel about these risks and that they should seek command or Component guidance before participating.  (2) If the HSR involves DoD-affiliated personnel, the key investigator must receive command or Component approval to execute the research.  (3) Military and civilian supervisors, officers, and others in the chain of command are prohibited from influencing their subordinates to participate in HSR.  (4) Military and civilian supervisors, officers, and others in the chain of command must not be present at any HSR participant recruitment sessions or during the HSR consent process for DoD-affiliated personnel. Excluded supervisors or those in the chain of command may participate in separate HSR recruitment sessions, if applicable.  (5) Service members and all Reserve Component and National Guard members in a federal duty status are considered for purposes of this issuance, 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.  (6) In order to approve research involving DoD-affiliated personnel as human subjects, the IRB or HRPO must determine whether the following requirements have been satisfied:  (a) The consent documentation must include, if applicable, potential risks for the revocation of clearance, credentials, or other privileged access or duty.  (b) For research involving recruitment of DoD-affiliated personnel in HSR determined greater than minimal risk, as defined by Part 219 of Title 32, CFR, and when HSR recruitment occurs in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:  1. Must not have a conflict of interest with the research or be a part of the research team.  2. 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.  3. Should be available to address DoD-affiliated personnel’s concerns about participation.  (7) Compensation to DoD-affiliated personnel for participation in research while on duty is prohibited in accordance with Title 5, U.S.C., with particular reference to Subparts G and H, with some exceptions for purposes consistent with Section 30 of Title 24, U.S.C. |  |
| **Biosafety DoDI 3216.02 1.2.e.**  Comply with all applicable biosafety and biosecurity requirements for activities conducted pursuant to this issuance; for example: DoD 6055.18-M, the current editions of Centers for Disease Control and Prevention, “Biosafety in Microbiological and Biomedical Laboratories (BMBL),” and the National Institutes of Health guidelines for research involving recombinant or synthetic nucleic acid molecules. |  |
| **International Research Policy:**  Conduct and support HSR outside of the United States in accordance with federal and DoD regulatory requirements and the host nation’s laws, as applicable. Host nation HSR laws are not typically applicable to DoD-conducted research that only involves DoD-affiliated personnel as research subjects. In cases when a DoD-affiliated person who is also a citizen of the host nation is a research subject, however, it is more likely that the host nation’s HSR laws will be applicable. DoD Components conducting and supporting HSR outside of the United States will consult with legal counsel, on a case-by-case basis, to determine whether host nation HSR laws are applicable. Where differences in applicable standards exist, the standard that is most protective of human subjects will be applied. |  |
| Require the key investigator to provide written notification to the U.S. Central, U.S. Africa, U.S. European, U.S. Indo-Pacific, and U.S. Southern Commands of HSR that is to be conducted or supported in their area of responsibility before HSR proceeds. This does not apply to research performed within the United States or at DoD institutions overseas. |  |
| **Policy on Collaborating with Non-DoD Institutions in Research** |  |
| **Policy on Detainees or Prisoners of War** |  |
| **3.7. DoD Assistance Program**  Will the COHRP outline an assistance program? |  |
| **3.16. Non-Compliance Reporting** |  |
| **3.17. CCHRPP Member** |  |
| **Continuity of Operations** |  |
| **HRPP Roles** |  |
| **Component Head DoDI 3216.02, 2.2.**  Grants permission for Component to conduct and/or support HSR |  |
| **SDO Selection 2.2.**  SDO selected by Component Head |  |
| **Commander/Director of Institutions:**  Under the authority, direction, and control of the SDO in the DoD Component, each commander or director of a DoD institution that conducts or supports HSR must: |  |
| Establish, implement, and maintain an HRPP to ensure the institution’s compliance with this issuance. |  |
| Provide experienced, well-qualified HRPP staff and appropriate resources needed to ensure compliance with this issuance. |  |
| Designate a HPD as the primary point of contact for the institution’s HRPP. |  |
| If conducting non-exempt research, identify an IO to establish and maintain a DoD assurance and other appropriate assurances. An alternate IO (AIO) may be appointed. |  |
| Evaluate and improve the institution’s HRPP, its policies, and its standard operating procedures. |  |
| Establish a program of post-approval compliance monitoring of HSR conducted or supported by the institution. |  |
| Provide well-qualified, experienced staff and sufficient resources commensurate with the Component’s research portfolio, appointing at least a GS-15 or equivalent federal employee to direct the CMP and subsequent HRPP. This individual’s experience in DoD-conducted and DoD-supported HSR, staff management, and systems of record must be commensurate with the scope of the HRPP. 2.2.d. |  |
| **IO/AIO** |  |
| **HPD** |  |
| **EDO** |  |
| **HRPO:**  All Federal Acquisition Regulation (FAR)–based contracts for DoD-supported research that include or may include HSR must contain the DFARS clause 252.235-7004 in its entirety in accordance with DFARS Section 235.072(e). |  |
| (a) All solicitations, including broad agency announcements, for DoD-supported research that include or may include HSR must contain the DFARS clause 252.235-7004, if the solicitation is for a FAR-based contract or substantially similar language if the solicitation is for a non-FAR-based agreement; and language referencing the National Policy Requirements Concerning Live Organisms Terms and Conditions, Section A.1., Human Subjects, at 81 Federal Register 78380, Appendix C to Part 1122. In addition to identifying DoD and non-DoD institutions’ responsibilities, the role of the HRPO is described in these two directives. |  |
| (b) Agreements other than contracts that include or may include HSR, but are not subject to DFARS clause 252.235-7004 (e.g., grants, assistance agreements), must state the non-DoD institution’s responsibilities. Including language referencing the National Policy Requirements Concerning Live Organisms Terms satisfies the requirements of this paragraph. |  |
| Contracts and other agreements (e.g., grants, assistance agreements) must:  (a) Restrict the performance of prospective DoD-supported HSR before the HRPO’s concurrence is provided.  (b) Be awarded before an official HRPO review is provided, although a non-binding HRPO review may be conducted before award. |  |
| DoD institutions must appoint or designate HRPO(s) to confirm that DoD-supported HSR complies with this issuance. |  |
| DFARS clause 252.235-7004 is not required to be included in a DoD agreement with another federal agency for DoD-supported HSR. However, these agreements must include language requiring the federal agency to apply Sections 3.8, 3.9, 3.10, 3.11 and 3.13 of this issuance, and Section 1520a of Title 50, U.S.C. |  |
| For non-exempt HSR, must submit to the HRPO:  1. Documentation that the DoD-supported HSR has been reviewed and approved by an IRB, including scientific merit, amendments, and additional reviews.  2. Documentation of key investigators’ human research protection training.  3. IRB-approved protocol documents.  4. Current FWA and IRB registration numbers. |  |
| For DoD-supported research that is exempt or does not involve human subjects, must submit institutional documentation of the determination that the research is either not HSR, exempt HSR, or limited IRB review to the HRPO, to include all protocol documents. |  |
| Must comply with all reporting requirements that may otherwise be applicable, in addition to the HRPO reporting and submission requirements in this section. |  |
| Must promptly notify the HRPO of the following:  1. IRB-approved changes to HSR that involve changes to key investigators or institutions; decreased benefit or increased risk to subjects in greater than minimal risk research as defined in Part 219 of Title 32; addition of vulnerable populations, or DoD-affiliated personnel as subjects.  2. Transfer of HSR oversight to a different IRB.  3. Notification by any federal body, State agency, official governing body of a Native American or Alaskan native tribe, other entity, or foreign government that the non-DoD institution’s DoD-supported HSR is under investigation.  4. Any problems involving risks to subjects or others, suspension or termination of IRB approval, or any serious or continuing noncompliance pertaining to DoD-supported HSR.  5. The results of the IRB’s continuing review, if required.  6. Change in status when a previously enrolled human subject becomes pregnant, or when the researcher learns that a previously enrolled human subject is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with Subpart B, Subpart 46 of Title 45, CFR.  7. Change in status when a previously enrolled human subject becomes a prisoner, and the protocol was not reviewed and approved by the IRB in accordance with Subpart C, Subpart 46 of Title 45, CFR.  8. A DoD-supported study’s closure.  9. Must make records that document compliance or noncompliance with this issuance accessible for inspection and copying, as determined by DoD HRPP personnel, by authorized DoD representatives. |  |
| 10. Will recognize that failure to comply with applicable requirements may result in the DoD:  a. Wholly or partially terminating or suspending the award;  b. Temporarily withholding payment under the award pending correction of the deficiency;  c. Disallowing all or part of the cost of the activity or action that is not in compliance; and/or  d. Contacting publishers of articles that reference the noncompliant HSR.  11. Will recognize that DoD-supported research should comply with the whole of this issuance when applicable. |  |
| **Reporting/SDO Reporting Responsibilities**  SDO Required Reporting 3.1. and other Reporting in the DOHRP Reporting Document |  |
| **Potential** **COHRP Waiver Requests:**  Required CMP elements may be modified upon waiver request by the COHRP or the prospective COHRP on behalf of the SDO for DOHRP approval. |  |
| Grants exceptions, consistent with law, to requirements in this issuance based on a written, appropriate justification from the senior designated official (SDO). 2.1.d. |  |
| Waiver for Single IRB Requirement |  |
| Ability to redact language in posted informed consent documents |  |
| Waive 10 USC 980 |  |
| Waive sending all LSGD studies to the DOHRP for review |  |
| Waiver to Implement Subparts  The DOHRP may delegate the authority for implementation of Subparts B, C, and D of Part 46 of Title 45, CFR, to the DoD Components’ SDOs within their CMP. |  |
| Notification of change in status when a previously enrolled human subject becomes pregnant, or when the researcher learns that a previously enrolled human subject is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with Subpart B, Subpart 46 of Title 45, CFR.  Change in status when a previously enrolled human subject becomes a prisoner, and the protocol was not reviewed and approved by the IRB in accordance with Subpart C, Subpart 46 of Title 45, CFR. |  |