*BY ORDER OF THE*
*SECRETARY OF THE AIR FORCE*

*DODI3216.02_DAFI40-402*

*17 JANUARY 2024*

*Medical Command*

# *PROTECTION OF HUMAN SUBJECTS AND ADHERENCE TO ETHICAL STANDARDS IN DAF-CONDUCTED AND -SUPPORTED RESEARCH*

**COMPLIANCE WITH THIS PUBLICATION IS MANDATORY**


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**OPR: DAF COHRP** **Certified by: AF/SG**

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**This publication implements Department of the Air Force (DAF) Policy Directive 40-4, "Protection of Animal and Human Subjects." This is in accordance with Headquarters of the Air Force Mission Directive 1-48, "The Air Force Surgeon General," which delegates authority and responsibility to AF/SG. DoDI 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research." is printed word-for-word in regular font without editorial review. DAF supplements are printed in bold font and indicated by "(Added)(DAF)." This supplement describes DAF requirements for protection of human subjects in DAF-conducted or –supported research. It applies to all DAF entities, including the Regular Air Force, Air National Guard, Air Force Reserve, and United States (U.S.) Space Force. It also applies to non-DoD entities which receive DAF support to conduct human research. Ensure all records generated as a result of processes prescribed in this publication adhere to AFI 33-322, "Records Management and Information Governance Program," and are disposed in accordance with the Air Force Records Disposition Schedule, which is located in the Air Force Records Information Management System. Refer recommended changes and questions about this publication to the office of primary responsibility (OPR) using the DAF Form 847, "Recommendation for Change of Publication;" route DAF Forms 847 from the field through the appropriate functional chain of command. This publication may be supplemented at any level, but all supplements must be routed to the OPR of this publication for coordination prior to certification and approval. The authorities to waive wing, unit, delta or garrison level requirements in this publication are identified with a Tier ("T-0, T-1, T-2, T-3") number following the compliance statement. See DAF Manual (DAFMAN) 90-161, "Publishing Processes and Procedures," Table A10.1, for Tier waiver authority definitions. Submit requests for waivers through the chain of command to the appropriate Tier waiver approval authority, or alternatively, to the publication OPR for non-tiered compliance items.**

**SUMMARY OF CHANGES**

**This document has been revised and should be completely reviewed. Major changes include procedures to implement the new DoDI 3216.02; inclusion of the Air Force Medical (AFMED) Agency role; new delegations of authority; a new requirement for scientific merit review for exempt human subject research; a new section on artificial intelligence; and revised human research protection program (HRPP) plan requirements.**

# DoD INSTRUCTION 3216.02

# PROTECTION OF HUMAN SUBJECTS AND ADHERENCE TO ETHICAL STANDARDS IN DoD-CONDUCTED AND -SUPPORTED RESEARCH

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**Originating Component:** Office of the Under Secretary of Defense for Research and Engineering

**Effective:** April 15, 2020
**Change 1 Effective:** June 29, 2022

**Releasability:** Cleared for public release. Available on the Directives Division Website at https://www.esd.whs.mil/DD/.

**Reissues and Cancels:** DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and Supported Research", November 8, 2011

**Approved by:** Michael Griffin, Under Secretary of Defense for Research and Engineering
**Change 1 Approved By:** Heidi Shyu, Under Secretary of Defense for Research and Engineering

**(Added)(DAF)** **ROBERT I. MILLER**
**Lieutenant General, USAF, MC, SFS**
**Surgeon General**

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**Purpose:** In accordance with the authority in DoD Directive 5137.02 and Part 219 of Title 32, Code of Federal Regulations (CFR), also known and referred to in this issuance as "the Common Rule," this issuance establishes policy, assigns responsibilities, and provides procedures for the protection of human subjects and adherence to ethical standards in DoD-conducted and supported research.

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# SECTION 1: GENERAL ISSUANCE INFORMATION

## 1.1. APPLICABILITY.

a. This issuance applies to:

(1) 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 (referred to collectively in this issuance as the "DoD Components").

(2) DoD Components and other organizational entities that issue, implement, update, and monitor a component human research protection program (HRPP) management plan (CMP) in order to conduct or support DoD research involving human subjects, such as the Defense Health Agency, the National Security Agency, the Defense Intelligence Agency, the DoD Human Resources Activity, the DoD Educational Activity, the Uniformed Services University of the Health Sciences, the Defense Acquisition University, the National Defense University, and the Special Operations Command.

(3) Human subject research (HSR) conducted or supported by the DoD (for DoD exclusions, see Glossary).

**(a) (Added)(DAF) The DAF supplemental material in this issuance applies to activities which meet the criterion of both paragraphs 1. and 2. below:**

**1. (Added)(DAF) Are (or are likely to include) the following activities, as defined by the Glossary:**

**a. (Added)(DAF) HSR, or**

**b. (Added)(DAF) Research involving large-scale genomic data (LSGD) (regardless of whether human subjects are involved).**

**2. (Added)(DAF) Are DAF-conducted, -supported, or -reviewed by an HSR review authority (see Table 1, HSR Research Review Authorities), in paragraph 2.8.a).**

**(b) (Added)(DAF) Note: Entities for which HSR oversight has transferred from DAF to the Defense Health Agency (DHA) are not considered DAF institutions for the purposes of this issuance.**

(4) Activities conducted or supported by the DoD, such as research, development, testing, and evaluation that involve humans, human data, human biospecimens, or activities regulated by the Food and Drug Administration (FDA).

**(a) (Added)(DAF) For FDA requirements applicable to protection of subjects in activities DAF-conducted or -supported activities, see Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), 312 (Investigational New Drug Application), 600 (Biological**

**Products), and 812 (Investigational Device Exemptions) of Title 21, CFR. Note: DAF-conducted and -supported activities which are FDA-regulated when conducted in the U.S. are also FDA-regulated when conducted in other countries.**

b. This issuance's applicability is not dependent upon the budget activities funding the research, the security classification of the research, the location of the research in the United States or a foreign country, or whether the research is conducted or supported by a program that is not considered research for other purposes. Guidance regarding this issuance is available on the Under Secretary of Defense for Research and Engineering (USD(R&E)) DoD Office for Human Research Protections (DOHRP) website https://rt.cto.mil/ddre-rt/dd-rtl/hsd/hrp/.

**c. (Added)(DAF) This issuance includes all DAF requirements necessary to implement the DoDI 3216.02 at the time of publication. If additional requirements are deemed necessary (e.g., to implement pending DoD guidance), this publication will be updated. When the DoDI 3216.02 or its references are updated, the DAF guidance in this issuance remains in effect (where more restrictive) pending publication of the updated DAF issuance.**

## 1.2. POLICY.

The DoD will:

a. Follow Part 219 of Title 32, CFR, and the Belmont Report (44 Federal Register 23192, April 18, 1979) principles, including respect for persons, beneficence, and justice.

b. Recognize that certain categories of human research subjects are vulnerable populations, in accordance with Subparts B, C, and D in Part 46 of Title 45, CFR, who are thus afforded additional protections, as specified in this issuance.

c. Recognize and adhere to Subpart E in Part 46 of Title 45, CFR.

d. Prohibit HSR for the testing of chemical or biological agents, 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 HSR can begin, the DoD Component seeking to conduct the HSR must receive explicit written approval from the DOHRP. The DOHRP will send a copy of the protocol and approvals for such research to the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs or any successor office.

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.

f. 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.

g. 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.

h. Require research involving large-scale genomic data (LSGD) collected from DoD-affiliated personnel to be subject to DoD Component security review and DOHRP approval, including the secondary use or sharing of de-identified data or specimens.

**(1) (Added)(DAF) See paragraph 3.10.**

i. Permit the use of broad consent, in accordance with Part 219 of Title 32, CFR, in DoD-supported research. DoD will permit use of broad consent in DoD-conducted and collaborative research pursuant to DOHRP guidance and with DoD Component notification to the DOHRP that a DoD institution intends to use broad consent in a research protocol.

j. Require use of a single institutional review board (IRB) in accordance with Section 219.114 of Title 32, CFR. If a DoD institution believes that the research is not subject to the provision listed in Section 219.114(b) of Title 32, CFR, the applicable DoD Component Office of Human Research Protections (COHRP) may determine and document, in accordance with Section 219.114(b)(2)(ii) of Title 32, CFR, that use of a single IRB is not appropriate for the particular context of the proposed HSR. Studies already in progress before January 20, 2020, will not be required to transition to a single IRB, nor submit exception documentation.

**(1) (Added)(DAF) The DAF COHRP Director (or their delegate) has authority to approve waivers in accordance with the above paragraph.**

k. Recognize that COHRPs have the authority to determine appropriate redactions when posting informed consent forms pursuant to Part 219 of Title 32, CFR, as presented by DoD institutions under their purview.

**(1) (Added) (DAF) The DAF COHRP Director (or their delegate) has authority to approve waivers in accordance with the above paragraph.**

l. Recognize that certain activities subject to this issuance are excluded from the requirements outlined in DoD Instruction (DoDI) 8910.01, Volumes 1 and 2 of DoD Manual 8910.01, and DoDI 1100.13. These include public or internal information collections of facts or opinions, obtained initially or in follow-up requests, from individuals (including individuals in control groups) under treatment or clinical examination in connection with research on, or prophylaxis to prevent, a clinical disorder; direct treatment of that disorder; or the interpretation of biological analyses of body fluids, tissues, or other

specimens; or the identification or classification of such specimens. These issuances may include other exclusions.

**(1) (Added) (DAF) Note: DoD internal information collection of facts or opinions from individuals in connection with HSR is not subject to licensing or approval requirements in accordance with DoDM 8910.01, Volume 1.**

**(2) (Added)(DAF) For DAF guidance on attitude and opinion surveys, see Air Force Manual 36-2664, "Personnel Assessment Program," Chapter 5.**

m. Not support or use funds for:

(1) The creation of a human embryo or embryos for research purposes, to include gene editing research; or

(2) Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of suffering, injury, or death greater than that allowed for research on fetuses in utero in accordance with Section 46.204(b) of Title 45, CFR, and Section 289g(b) of Title 42, U.S.C.

n. Ensure DoD-supported fetal research complies with Section 289g(b) of Title 42, U.S.C. and Subpart B of Section 46 of Title 45, CFR, as described in Paragraphs 3.1, 3.5, 3.6, and 3.9 of this issuance.

**o. (Added)(DAF) The DAF assures all of its activities will comply with the DoD policy of this section to the extent applicable. The DAF has not issued additional policies related to the protection of human subjects or adherence to ethical standards in DAF-conducted and-supported research.**

## 1.3. SUMMARY OF CHANGE 1.

This change updates policy to better reflect current restrictions on the creation of a human embryo or embryos for research purposes, to include gene editing or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of suffering, injury, or death greater than that allowed for research on fetuses in utero. This change also updates references.

# SECTION 2: RESPONSIBILITIES

## 2.1. USD(R&E).

The USD(R&E):

a. Is the:

(1) DoD point of contact for all matters related to DoD compliance with this issuance.

(2) Principal DoD liaison with agencies and organizations outside the DoD on matters pertaining to HSR, including ethics and privacy concerns in research as they relate to HSR.

b. Provides procedures and guidance necessary to implement this issuance.

c. Exercises:

(1) The authorities of:

(a) The department head identified in Part 219 of Title 32, CFR.

(b) The Secretary of Defense identified in Section 980 of Title 10, U.S.C.

(c) The Secretary of Defense for Subparts B-E of Part 46 of Title 45, CFR.

(2) The authority, direction, and control of the DOHRP to:

(a) Halt studies and rescind or limit authorities granted to DoD Components' HRPPs, as needed.

(b) Accept and approve each DoD Component's CMP, implementing and supporting policies or any modifications thereto, and provide oversight of the plan's implementation for compliance with this issuance. A DOHRP-approved CMP must be in place before DoD Components conduct or support any research involving human participants. The direct oversight of the DoD Component's implementation of its CMP and subsequent HRPP is with the DOHRP.

(c) Establish guidance for:

1. DoD Component human subject protection training.

**a. (Added)(DAF) See Office of the Assistant Secretary of Defense for Research and Engineering Memorandum, "Minimum Education Requirements for DAF Personnel Involved in Human Research Protection," August 16, 2012.**

2. DoD Component security review of research involving LSGD collected on DoD-affiliated personnel, to include administrative, technical, and physical safeguards for protecting their confidentiality both during and after the conduction of research.

3. DoD Component review of the ethical, legal, and social implications of emerging, readily available technologies or controversial research, development, testing, and evaluation.

4. Mandatory submittal document for all DoD-supported HSR.

(d) Performance of site visits to and inspections of DoD and non-DoD institutions that conduct research, or receive DoD support, as applicable, with or without prior notice.

d. Grants exceptions, consistent with law, to requirements in this issuance based on a written, appropriate justification from the senior designated official (SDO).

e. Delegates DOHRP authorities as appropriate.

f. Provides procedures in accordance with this issuance for use of certificates of confidentiality (CoCs).

g. Designates DoD representatives to federal committees as appropriate.

h. Establishes and coordinates the activities of the DoD Coordinating Committee for HRPPs (CCHRPP), along with its Executive Secretariat, the DOHRP Cabinet (DC). The DC is the central advisory body to the DoD, USD(R&E), and the DOHRP on matters outlined in this issuance.

i. Conducts Component HRPP assessments every other year.

j. Maintains:

(1) A list of classified HSR.

(2) Lists of DoD IRBs and DoD Institutional Biosafety Committees.

k. Designates:

(1) The Director, Human Systems Directorate, who chairs the CCHRPP and oversees the Director, DOHRP.

(2) The Director, DOHRP the authority for the operations of the DOHRP, and the designated manager for this issuance.

## 2.2. DOD COMPONENT HEADS.

The heads of DoD Components that conduct or support HSR:

a. Issue, implement, update, and monitor the CMP for implementing this issuance and guidance or memoranda pursuant to this issuance.

**(1) (Added)(DAF) This issuance serves as the DAF CMP; it supersedes all prior versions. See also paragraph 3.2.**

**(2) (Added)(DAF) This CMP remains valid until this issuance is superseded by new guidance or rescinded in accordance with DAFMAN 90-161.**

**(3) (Added)(DAF) The DAF COHRP will obtain DOHRP approval of any modifications to this CMP prior to publication. DAF institutions' HRPPs and DoD assurances remain in effect during any such DOHRP review to the extent they do not expire, are not suspended, or are not terminated in accordance with this issuance.**

b. Identify the SDO, who will either hold the rank of general officer/flag officer or be a member of the Senior Executive Service, and will have the authority to implement the CMP.

**(1) (Added)(DAF) The DAF SDO is the Surgeon General (AF/SG). See paragraph 2.3.**

c. Establish a COHRP with authority and responsibility for the CMP and regulatory oversight of Component HSR at its office and its institutions.

**(1) (Added)(DAF) The DAF COHRP Director is within the office of the AF/SG. See paragraph 2.5.**

d. 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.

**(1) (Added)(DAF) The AF/SG is delegated responsibility to ensure the DAF COHRP has appropriate staff and resources. See paragraph 2.3.c.**

e. Provide members to intra- and interagency committees, the CCHRPP, and the DC when requested.

**(1) (Added)(DAF) The DAF provides members to the committees described in the paragraph above in accordance with paragraphs 2.3.d (in general); 2.4.c (specific to the CCHRPP); and 2.5.h (specific to the DC).**

f. Require that all Component institutions and sub-institutions that conduct or support HSR have a Component-approved HRPP.

**(1) (Added)(DAF) The DAF COHRP ensures compliance with the above paragraph in accordance with paragraphs 2.5.b, 3.2.a.(3)(a), and 3.3.**

g. Provide an index of all DoD-conducted or DoD-supported HSR to the DOHRP before the end of each fiscal year.

## 2.3. (ADDED)(DAF) THE DEPARTMENT OF THE AIR FORCE SURGEON GENERAL (AF/SG).

**(Added)(DAF) The AF/SG:**

**a. (Added)(DAF) Is the DAF SDO. While the AF/SG may not further delegate the SDO position, this issuance delegates certain responsibilities necessary for compliant implementation of the DAF HRPP.**

**(1) (Added)(DAF) As such, is responsible for the DAF HRPP, the purpose of which is to:**

**(a) (Added)(DAF) Protect human subjects in research conducted or supported by the U.S. Air Force and the U.S. Space Force.**

**(b) (Added)(DAF) Ensure DAF-wide compliance with the requirements established herein.**

**(2) (Added)(DAF) The source of DAF SDO authority is as follows:**

**(a) (Added)(DAF) The delegation of the Secretary of the Air Force's authority and assignments of responsibility are documented in Headquarters of the Air Force (HAF) Mission Directive 1-48, "The Air Force Surgeon General."**

**(b) (Added)(DAF) USD(R&E) authority, exercised through the DOHRP, to accept and approve the DAF Component Management Plan (CMP) (i.e., this issuance) per paragraph 2.1.c.(2)(b).**

**b. (Added)(DAF) Oversees implementation of the DAF CMP (i.e., the DAF-level HRPP). Approves this CMP and any updates. Develops, issues, implements, and monitors this DAF CMP through the DAF COHRP.**

**c. (Added)(DAF) Ensures the DAF COHRP is staffed and resourced in accordance with paragraph 2.2.d.**

**d. (Added)(DAF) Provides subject matter expertise to the DAF COHRP, when requested, e.g., via the AF/SG consultants. Provides members to intra- and interagency committees, when requested, in accordance with paragraph 2.2.e.**

**e. (Added)(DAF) Ensures the DAF COHRP forwards to the DOHRP all items required in DoDI 3216.02 (e.g., in paragraphs 2.2.g (the index of DAF-conducted or -supported HSR), 3.1 (various reports), and 3.13 (classified HSR)).**

**f. (Added)(DAF) Receives an annual executive briefing from the DAF COHRP on the status of the DAF HRPP, including:**

**(1) (Added)(DAF) The annual index of all DAF-conducted or -supported HSR required for submission to the DOHRP per paragraph 2.2.g.**

**(2) (Added)(DAF) Human subject protection training in accordance with paragraph 2.1.c.(2)(c)1.**

## 2.4. (ADDED)(DAF) AIR FORCE MEDICAL AGENCY COMMANDER (AFMED AGENCY/CC).

**(Added)(DAF) AFMED Agency/CC:**

**a. (Added)(DAF) Supports the AF/SG in implementation of their DAF-wide responsibilities identified in paragraphs 2.2 and 2.3. Maintains the DAF Component Office of Human Research Protections (COHRP) to support execution of the DAF HRPP, including this CMP, in accordance with Air Force Mission Directive 35, "Air Force Medical Readiness Agency." [Note: the Air Force Medical Readiness Agency was redesignated as AFMED Agency on 1 October 2023.]**

**b. (Added)(DAF) Establishes and maintains an HRPP plan to ensure AFMED Agency-conducted or supported HSR complies with this issuance. See also section 3.3.**

**c. (Added)(DAF) Serves as the regular DAF CCHRPP member in accordance with paragraph 2.2.e and section 3.17. Completes human subject protection training required for CCHRPP members.**

## 2.5. (ADDED)(DAF) DAF COMPONENT OFFICE OF HUMAN RESEARCH PROTECTIONS (COHRP).

**(Added)(DAF) The DAF COHRP is located within the Air Force Medical Service, which encompasses the organizations of AF/SG (responsible for policy and oversight) and AFMED Agency (responsible for execution). The DAF COHRP performs the following functions on behalf of the SDO (AF/SG):**

**a. (Added)(DAF) Is responsible for implementation of the CMP (i.e., the DAF-wide HRPP plan included in this issuance). Improves the DAF HRPP, as needed, e.g., by updating this issuance. Writes, coordinates, and maintains guidance for the DAF HRPP. Consults on requirements and best practices (e.g., for DAF HRPP resources and staffing). May provide written delegation of COHRP authorities, as appropriate, unless restricted herein. The DAF COHRP includes the Director and support staff.**

**(1) (Added)(DAF) Is led by a DAF COHRP Director. The Director is responsible for policy and oversight of the DAF HRPP. The Director assesses compliance of DAF HRPP plan implementation, spanning from DAF COHRP personnel in AFMED Agency to the institutional level.**

**(2) (Added)(DAF) Is supported by the DAF COHRP staff in AFMED Agency. This office is responsible for supporting execution of the DAF HRPP, including this CMP (e.g., provision of training and review of proposed activities).**

**b. (Added)(DAF) Reviews, approves, and oversees DAF institution-level HRPP plans and assurances in accordance with paragraphs 3.2 - 3.4. Ensures each DAF institution has appropriate human research protection documentation in place before and throughout their conduct of or support to HSR.**

**c. (Added)(DAF) Ensures compliance of proposed DAF-conducted or -supported activities which are (or are likely to include) HSR by performing exemption determination official (EDO) review, human research protection official (HRPO) review, and/or component-level administrative review (CLAR), as needed. Will maintain human subjects protection expertise (e.g., through appropriate staffing, training, and inquiry into evolving technologies or techniques, etc., as needed) in support of the DAF HRPP. Will consult with others (e.g., AF/SG consultants) to obtain expertise in other areas (e.g., medical, social-cultural, and operational), as needed.**

**d. (Added)(DAF) The DAF COHRP Director delegates authority, in writing, to DAF personnel to perform EDO or HRPO review. Before delegating EDO or HRPO authority, will ensure compliance with paragraph 2.8, including verification the proposed delegate's HRPP includes procedures for each delegated HSR review authority type.**

**e. (Added)(DAF) Implements initial and ongoing role-based human subject protection training requirements established in accordance with paragraph 2.1.c.(2)(c)1. Updates training, as needed. Either provides the training or identifies acceptable sources of equivalent training.**

**f. (Added)(DAF) Encourages collaboration among DAF institutions with HRPPs. Encourages feedback to meet DAF-wide mission needs. Works with the DOHRP to ensure DAF HRPP personnel receive timely written notice of any DOHRP actions or guidance impacting their institution(s), when possible. Creates and facilitates execution of a communications plan to ensure DAF-wide awareness of and compliance with this issuance (e.g., including communications for AF/SG distribution).**

**g. (Added)(DAF) On behalf of the SDO, ensures compliance with higher-level reporting and related requirements of the DoDI 3216.02 (e.g., in paragraphs 2.2.g (an index of DAF-conducted or -supported HSR), 3.1 (reports), and 3.13 (classified HSR)) and its references. Ensures each item requiring a report is identified, appropriately addressed, and submitted to the DAF COHRP. Channels all such reports to the appropriate higher-level authorities (e.g., the SDO or DOHRP), as required. Provides an annual executive briefing to the SDO in conjunction with the index of DAF HSR reported to the DOHRP per paragraph 2.2.g.**

**h. (Added)(DAF) Performs other functions identified in this issuance or as assigned by the AF/SG or AFMED Agency. The DAF COHRP Director serves as the primary DAF member of the DC and other DAF and DoD HRPP advisory committees.**

**i. (Added)(DAF) Maintains records of DAF COHRP activities in accordance with Air Force Records Information Management System requirements.**

## 2.6. (ADDED)(DAF) COMMANDERS OR DIRECTORS OF DAF INSTITUTIONS.

**(Added)(DAF) Each DAF Commander or Director of a DAF institution will comply with the procedures of section 3.3.**

## 2.7. (ADDED)(DAF) HUMAN PROTECTIONS DIRECTORS (HPD).

**(Added)(DAF) Each HPD of a DAF institution with an HRPP will:**

**a. (Added)(DAF) Ensure compliant administration of the institution's HRPP in accordance with this issuance, its references, and the HRPP plan. Monitor all HSR review authority determinations issued either by the institution's personnel, or by another institution for activities the institution conducts or supports.**

**b. (Added)(DAF) Serve as the institution's primary point of contact for the DAF COHRP. Review and promptly report to the institutional official (IO) and the DAF COHRP any item that requires reporting to or review by the DAF COHRP, DOHRP or other higher-level authorities in accordance with this issuance and its references.**

**c. (Added)(DAF) Receive written designation as the HPD in accordance with the institution's HRPP prior to acting in this capacity.**

**d. (Added)(DAF) Encourages collaboration among institutional HRPP personnel. Encourage feedback to meet institution-wide mission needs.**

**e. (Added)(DAF) Prepare briefings on the HRPP (e.g., for the IO), as needed.**

## 2.8. (ADDED)(DAF) DAF HSR REVIEW AUTHORITIES.

**Each DAF HSR review authority (i.e., exemption determination official (EDO), institutional review board (IRB), human research protection official (HRPO), and component-level administrative review (CLAR) authority) will comply with the respective requirements of this section. .**

**a. (Added)(DAF) Review DoD-conducted or –supported activities which are (or are likely to include) HSR to ensure compliance with this issuance before initiation. Facilitate HSR conducted or supported by more than one DoD institution by minimizing duplication of required reviews, when possible, through deferral to equivalent HSR review authorities. Have authority to issue requirements, based on their interpretation of this issuance and its references. Table 1 summarizes all DAF HSR review authorities for DoD-supported and DoD-conducted activities that include (or are likely to include) HSR.**

**(Added)(DAF) Table 1. HSR Review Authorities.**

| HSR review authority functions | Primary references herein[1] | The HSR review authority type is required when the DAF institution: | Actions[6] |
|---|---|---|---|
| EDO[2, 3] | 2.8.f | Conducts activities that include or may include HSR (see paragraph 3.5) | Determine to be:<br>- Not research<br>- Not HSR<br>- Exempt HSR<br>- Non-exempt HSR requiring IRB review |
| IRB[2, 5] | 2.8.g and 3.3.h.(6)(b) | Conducts activities that include or may include HSR (see paragraph 3.5)<br>Supports collaborative non-DoD conducted activities that include (or are likely to include) HSR (see paragraphs 3.6.b.(5) and 3.7) | For activities that are not research, not HSR, or exempt HSR, determine to be:<br>- Not research<br>- Not HSR<br>- Exempt HSR<br><br>For non-exempt HSR:<br>- Approve<br>- Approve with conditions<br>- Disapprove[7] |
| HRPO[3, 4] | 2.8.h | Supports non-DoD conducted activities that include (or are likely to include) HSR (see paragraphs 3.6 and 3.7) | After successful completion of non-DoD IRB (or similar) review:<br>- Concur with the non-DoD IRB's determination<br>- Nonconcur[7] with the non-DoD IRB's determination |
| CLAR[3, 4,] | 2.5.c and 2.8.i | Conducts (per paragraph 3.5.b) or supports (per paragraph 3.6.a) specified types of non-exempt HSR | - Approve<br>- Approve with conditions<br>- Disapprove[7] |

**Notes:**

1. **This table only identifies the primary references in this issuance specific to each HSR review authority type; review full publication for all directive guidance.**
2. **This function is an initial review to ensure compliance of the activity.**
3. **The COHRP has authority to perform (and delegate performance of) EDO, HRPO, and CLAR functions. DAF institutions may request delegation of this authority from the DAF COHRP Director per paragraph 2.8. DAF HSR review authorities with existing delegation from the DAF COHRP as of the date of this issuance remain in effect (to the extent they do not expire or are otherwise limited).**
4. **This function is a second-level administrative review to ensure compliance of both the activity and the initial HSR review. This function cannot be used to approve an activity which received disapproval or nonconcurrence in the initial HSR review.**
5. **The primary purpose of a DAF IRB is to review activities a DAF institution conducts. However, it can perform HRPO reviews of non-DoD conducted activities that include (or are likely to include) HSR in accordance with paragraphs 3.6.b.(5) and 3.7.**
6. **Action indicating successful completion of each research type is underlined.**

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|---|
| **7. Any disapproval (or equivalent) will include a written a statement of the reasons for the decision and provide the investigator opportunity to respond in writing.** |

**b. (Added)(DAF) Meet the following requirements before making a determination:**

**(1) (Added)(DAF) Complete required training (per paragraph 2.5.d). (T-0) IRB members receive written delegation from their IO. EDOs, HRPOs, and CLAR officials will receive written delegation of authority from the DAF COHRP Director and their IO. Such delegations are not further delegable unless specifically permitted by this issuance or the DAF COHRP Director, in writing.**

**(2) (Added)(DAF) Ensure their institution's HRPP includes procedures for performance of the HSR review authority function. If this requires a change to the institution's HRPP plan, obtains DAF COHRP approval thereof. (T-0)**

**(3) (Added)(DAF) Ensure they do not have a conflict of interest in review of the activity. (T-0) For example, a program manager will not serve as a HRPO for activities they manage. Disclose potential conflicts of interest (e.g., to the HPD) for mitigation.**

**c. (Added)(DAF) Perform timely reviews to ensure compliance (e.g., with this issuance, its references, and the institution's HRPP plan), reduce administrative burden, and minimize research delay. Obtain and review documentation necessary to support the determination to be made. Document and maintain records of each determination in accordance with paragraphs 3.5.a.(7)(a) and 3.6.a.(4).**

**d. (Added)(DAF) Submit to the DAF COHRP any research requiring review by higher-level authorities (e.g., waiver of informed consent under Section 980 of Title 10, U.S.C.) prior to start. (T-0) Include in determinations provided for such activities clear language informing investigators they must not begin until after completion of such higher-level review. (T-0)**

**(1) When seeking to permit DoD-conducted HSR using broad consent, submit documentation that the broad consent is permissible in light of the requirements identified in paragraph 1.2.i to the DAF COHRP, which submits the notification to the DOHRP. (T-3)**

**e. (Added)(DAF) Review and promptly report to the supporting and conducting IO(s), plus the DAF COHRP, any items that require reporting to the DAF COHRP, DOHRP, or other higher-level authorities per this issuance or its references. (T-0)**

**f. (Added)(DAF) In addition to the requirements of paragraphs 2.8.a-e, when serving as a DAF exemption determination official (EDO), will:**

**(1) (Added)(DAF) Review activities that include (or are likely to include) HSR per Section 219.102 of Title 32, CFR, to ensure compliance with applicable requirements of this publication and to determine and document which of the following categories applies: (T-0)**

**(a) (Added)(DAF) Not research.**

**(b) (Added)(DAF) Research not involving human subjects.**

**(c) (Added)(DAF) Exempt HSR (see Glossary, i.e., HSR which is exempt from the requirement for IRB review per Section 219.104 of Title 32, CFR).**

**(d) (Added)(DAF) HSR that requires IRB review prior to start per Part 219 of Title 32, CFR.**

**(2) (Added)(DAF) Comply with the special considerations identified in this publication, including those described at paragraph 3.5.a.(7)(a).**

**(3) (Added)(DAF) Notify the key investigator of the determination and, if the activity requires IRB approval prior to start, refers to a DAF IRB.**

**(4) (Added)(DAF) When the DoD-conducted activity is a collaboration involving a non-DoD institution, ensure any related non-DoD conducted activities covered by a non-DoD HRPP determination (e.g., from a non-DoD IRB) receive HRPO review prior to start.**

**g. (Added)(DAF) In addition to the requirements of paragraphs 2.8.a-e, when serving as a DAF Institutional Review Board (IRB) chair, will:**

**(1) (Added)(DAF) Lead IRB reviews of activities that include (or may include) HSR in accordance with Part 219 of Title 32, CFR. See also Part 219 of Title 32, CFR for procedural requirements for "convened" review; "expedited" review by the IRB chair or by one or more experienced IRB reviewers designated by the chair in accordance with Section 219.110 of Title 32, CFR; and "limited IRB" review pursuant to Sections 219.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), or (d)(8) of Title 32, CFR.**

**(2) (Added)(DAF) Preferably have at least one year of experience as a member of an IRB and demonstrated knowledge of HRPP requirements.**

**(3) (Added)(DAF) Appoint a vice chair, when appropriate, to fulfill these duties in the absence of the IRB chair.**

**(4) (Added)(DAF) Ensure the IRB considers scientific merit and reviews for research in accordance with the requirements of this issuance and its references. (T-0)**

**(5) (Added)(DAF) Ensure IRB minutes document actions and determinations, e.g., as required per Section 219.115 of Title 32, CFR, and as necessary to memorialize resolution of compliance issues. (T-0) Review and sign minutes to verify accuracy.**

**(6) (Added)(DAF) Consult with other committees, as appropriate (e.g., radiation committee, safety committee, privacy board), to assess HSR under the IRB's purview.**

**(7) (Added)(DAF) Accept DoD assurances issued by other DoD Components, and accepts other Federal assurances from non-DoD institutions, as appropriate for the scope of HSR. (T-0)**

**h. (Added)(DAF) In addition to the requirements of paragraphs 2.8.a-e, when serving as a DAF human research protection official (HRPO), will:**

**(1) (Added)(DAF) Review non-DoD institution's supported activities which include (or are likely to include) HSR (as indicated by their agreement with DoD (e.g., contract, cooperative research and development agreements, and other agreement)) to ensure compliance with this issuance. When more than one DoD institution provides support, the HRPO of the institution executing an agreement to provide support to the non-DoD institution's activities is the HRPO of record (unless deferred to an equivalent HSR review authority in accordance with paragraph 2.8.a).**

**(2) (Added)(DAF) Provide advice on HRPP requirements applicable to DAF supported HSR conducted by non-DoD institutions (e.g., share their HRPO determination checklist to enable investigators to anticipate and meet requirements). Coordinate with appropriate personnel (e.g., government contracting officer or DoD program manager) to obtain necessary documentation and information to enable approval and continuing oversight, as required.**

**(3) (Added)(DAF) Promptly review all reports required by DoDI 3216.02 (e.g., per paragraph 3.1) related to any HSR under the HRPO's purview. Submit the reports to the DAF COHRP, supported by facts and appropriate regulatory citations, including any recommendations necessary to ensure continued protection of human subjects. Send a courtesy copy on related communications to the supporting DoD institution(s). The DAF COHRP will notify the DOHRP.**

**(4) (Added)(DAF) Acknowledge receipt, in writing (e.g., by e-mail), of each non-DoD institution's certification submitted to the HRPO in accordance with the paragraph 3.6.b. Notify the supporting DoD institution and the conducting non-DoD institution in writing, of the HRPO determination.**

**(5) (Added)(DAF) When the non-DoD-conducted activity is a collaboration involving a DoD institution, ensure the DoD-conducted activities receive IRB or EDO review, as required, prior to start in accordance with paragraph 3.5. (T-0)**

**(6) (Added)(DAF) Accept DoD assurances issued by other DoD Components, and accepts other Federal assurances from non-DoD institutions, as appropriate. (T-0)**

**i. (Added)(DAF) In addition to the requirements of paragraphs 2.8.a-e, when serving as a component-level administrative review (CLAR) authority, will:**

**(1) (Added)(DAF) Review DoD-conducted or –supported activities after IRB approval (and after HRPO approval, if the activity is DoD-supported) in accordance with paragraphs 3.5.b and 3.6.a. Generally, the COHRP performs CLAR. However, the COHRP may delegate authority to HSR review authorities at DAF institutions with HRPPs approved to include the CLAR function. Any such delegation will specify that CLAR must be performed either above the level of, or completely separate from, the institution performing the IRB or HRPO determination of the HSR under review.**

**(2) (Added)(DAF) Notify the supporting and/or conducting DoD institution and any conducting non-DoD institution of the CLAR determination.**

## 2.9. (ADDED)(DAF) KEY INVESTIGATORS.

**(Added)(DAF) Each key investigator of activities that include (or are likely to include) HSR will:**

**a. (Added)(DAF) Promptly comply with direction of the applicable HSR review authority regarding compliance with this issuance and other requirements. Manage and is responsible for supervision of all HSR conducted under the key investigator on behalf of the engaged institution(s).**

**b. (Added)(DAF) Prior to start of an activity that includes (or are likely to include) HSR, obtain the following documentation in accordance with the institution's HRPP.**

**(1) (Added)(DAF) If the HSR involves DoD-affiliated personnel or facilities, documentation required by paragraphs 3.5.a.(6) and 3.9.f.(2), as applicable.**

**(2) (Added)(DAF) Either of the following determinations, as applicable, per Part 219 of Title 32, CFR.**

**(a) (Added)(DAF) An IRB determination that the activity is not research, is not HSR, is exempt HSR, or is approved non-exempt HSR.**

**(b) (Added)(DAF) An EDO determination that an activity is not research; is not HSR; or is exempt HSR. (T-0)**

**c. (Added)(DAF) Notify DAF HSR review authorities with purview over their activity (e.g., their IRB or HRPO) of unanticipated problems involving risks to subjects or others and non-compliance. (T-0) Propose protocol changes to minimize risks to subjects, as needed. (T-0)**

**d. (Added)(DAF) Report conflicts of interest in accordance with their institution's HRPP plan. (T-0)**

**e. (Added)(DAF) Maintain HSR records for a minimum of three years after the research ends or for the period required by applicable regulations, institutional requirements, or sponsor requirements, if longer than three years. (T-0) Include all records related to the HSR. (T-0) After completing HSR or upon reassignment, provide HSR records for storage to the institution under which the research was conducted.**

# SECTION 3: PROCEDURES

## 3.1. DOD SDOS.

The SDO of a DoD Component that conducts or supports HSR:

a. Will provide to the DOHRP, through the COHRP, copies of human subject protections-related substantive communications or reports provided to the White House, federal courts, the FDA, congressional staff, committees, or State or local representatives within 5 business days after learning of the communications or reports.

b. Will provide to the DOHRP, through the COHRP, copies of waivers to this issuance granted to a COHRP on behalf of the SDO, if given the authority by the DOHRP, within 5 business days of issuing the waiver. This reporting requirement does not apply to waivers as described throughout Part 219 of Title 32, CFR, issued by institutional officials (IOs) or IRBs (i.e., waivers of documentation of informed consent or waivers of informed consent).

c. Will provide to the DOHRP, through the COHRP, approvals and documentation of HSR in fetal research as described in Sections 289g–289g-2 of Title 42, U.S.C. The SDO must obtain written approval from the DOHRP before HSR activities involving fetal research may begin.

d. Will provide to the DOHRP, through the COHRP, approvals and documentation of protocols requiring certification from the SDO that the reviewing IRB has fulfilled its duties in accordance with Subpart B of Part 46 of Title 45, CFR, for research that would not otherwise be approved but for the fact that it presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates. The SDO must obtain written approval from the DOHRP before permitting any HSR to be conducted that involves research that would not otherwise be approved but for the fact that it presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

e. Will provide to the DOHRP, through the COHRP, approvals of HSR requiring a waiver to Section 512 of the E-Government Act of 2002 (Public Law 107-347), and the notice to the Office of Management and Budget, pursuant to the E-Government Act of 2002 and Pages 33362-33377 in Volume 72, Federal Register, within 5 business days of approving the HSR.

f. Will provide to the DOHRP, through the COHRP, reports of for-cause audits, reviews, or assessments conducted by or on behalf of the COHRP within 5 business days of writing the document.

g. Will provide to the DOHRP, through the COHRP, reports of audits of DoD-conducted or DoD-supported HSR by another federal or State agency, official governing body of a Native American or Alaskan native tribe, other official entity, or foreign government, within 5 business days of discovering that such audit reports exist.

h. Will provide to the DOHRP, through the COHRP, reports required in accordance with Title 32, CFR, or similar reports upon request by the DOHRP, within 5 business days of the report's completion, pertaining to:

(1) Allegations of serious or continuing noncompliance related to HSR that are substantiated by investigation, and subsequent actions taken based on the findings;

(2) Unanticipated problems involving risks to human subjects or others and subsequent actions taken based on the findings; or

(3) Suspensions or terminations of IRB approval.

i. Will submit written justification to the DOHRP to establish a new IRB, or substantially modify an IRB, at a minimum of 120 business days before establishment or modification for DOHRP concurrence. Will notify the DOHRP at least 120 business days before disestablishing an IRB.

j. Will provide details of DoD Component security reviews to the DOHRP, more than OR at least 30 business days before beginning research involving LSGD collected from DoD-affiliated personnel.

**(1) (Added)(DAF) Will submit such security reviews to the DOHRP, through the COHRP, in accordance with paragraph 3.10. (T-3) Note: The USD(R&E) has granted an exception from the above requirement to submit security reviews to the DOHRP before beginning LSGD research for which DOHRP approval has been waived. See also paragraph 3.2.a.(3)(c)1.**

**k. (Added)(DAF) Will provide submissions to the DOHRP, through the COHRP, in accordance with the following general process. (T-3) See also paragraph 2.5.g.**

**(1) (Added)(DAF) The DAF institution conducting or supporting the HSR at issue compiles the package, including a memorandum summarizing the submission, and provides it to the DAF COHRP. The DAF COHRP Director coordinates the package with the DAF SDO, if required. The DAF COHRP will work with the submitter to address any unresolved issues, as required. (T-3)**

**(2) (Added)(DAF) The DAF COHRP will facilitate timely review of activities, as needed, to minimize research delay.**

## 3.2. CMP.

a. The CMP must:

(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.

**(a) (Added)(DAF) This issuance is the DAF CMP. It identifies all DAF policies and guidance to implement DoDI 3216.02 and its references.**

(2) Identify the SDO with the authority and responsibility for implementing the CMP.

**(a) (Added)(DAF) See paragraph 2.3.**

(3) Be consistent with DOHRP guidance and include or reference DoD Component policies and procedures, if applicable, that:

(a) Establish authority for, and include or reference policies under which, the COHRP will issue, limit, or revoke DoD assurances upon assessment of institutions' HRPPs.

**1. (Added)(DAF) The DAF COHRP Director approves each DAF institution's new, renewed, and substantively changed HRPP plan, including any associated DAF-issued DoD assurance, prior to implementation and after ensuring compliance. (T-0) This authority will not be further delegated. (T-0) HRPP plans and DoD assurances are approved for three year time periods; deviations are permitted with the DAF COHRP Director's written justification.**

**2. (Added)(DAF) The DAF hereby accepts DoD assurances issued by other DoD Components to other DoD Component institutions. The DAF also hereby accepts other Federal assurances issued to non-DoD institutions. Authority to accept assurances flows to DAF IRB chairs (and, for the purposes of expedited IRB procedures, their IRB member designee(s)) and DAF human research protection officials (HRPOs), but cannot be further delegated. DAF HRPP personnel approval of non-exempt HSR constitutes acceptance of related assurances.**

**3. (Added)(DAF) The DAF COHRP Director has authority to suspend, limit, or revoke the items identified in the subparagraphs below in order to ensure protection of human subjects (e.g., upon identification of likely serious or continuing noncompliance meriting such action). When exercising such authority, will provide to the SDO and the IO of each affected conducting or supporting institution (or, if no IO, to their commander or equivalent leader) a statement of the reasons for this action and opportunity to respond in writing.**

**a. (Added)(DAF) DAF COHRP Director approval of DAF-issued DoD assurances or HRPPs.**

**b. (Added)(DAF) Any DAF-conducted or -supported activity that is (or is likely to include) HSR. Note: Action to "revoke" such activity means termination of DAF HSR review authority coverage for the activity required by DoDI 3216.02; this effectively will end the DAF conduct of or support to HSR.**

**4. (Added)(DAF) The DAF COHRP will provide HRPP staff assistance visits (in person or remote) when requested by a DAF institution's commander. The purpose is to help the institution better understand the intent of this issuance and to provide training. Staff assistance visits are not compliance assessments or inspections.**

**5. (Added)(DAF) The DAF COHRP performs compliance assessments for cause (e.g., due to potential serious or continuing noncompliance; see para 3.2.a.(3)(a)5.f below) and not-for-cause (i.e., as routine periodic audits, or per requests for initial or renewed approval of DoD assurances and HRPPs; see paras 3.2.a.(3)(a)5.a. – e. below). The DAF COHRP performs compliance assessments using tools to be provided in advance (e.g., with the assessment announcement).**

**a. (Added)(DAF) Compliance assessments performed per requests for initial or renewed approval of DoD assurances and HRPPs (i.e., not-for-cause) will include both review of appropriate HRPP documentation and site visits (in person or remote, as appropriate). The purpose of such visits is to assess compliance of each institution's HRPP. The DAF COHRP will schedule these visits with appropriate gatekeepers in accordance with DAFI 90-302, "The**

**Inspection System of the Department of the Air Force." These visits will include the elements identified in Table 2, DAF HRPP Compliance Assessment Elements.**

**(Added)(DAF) Table 2. DAF HRPP Compliance Assessment Elements.**

| # | DAF HRPP Compliance Assessment Element |
|---|---|
| 1. | An in-brief and out-brief with the IO, human protections director (HPD), and appropriate HRPP personnel, if possible. |
| 2. | Review of the institution's HRPP plan and related implementation records (e.g., procedures for implementation of the HRPP, human subject protection training records, and documentation of completion of post-approval compliance monitoring). |
| 3. | Review of a sample of records related to activities which the institution conducted, supported, or reviewed via its personnel serving as HSR review authorities per Table 1 (see paragraph 2.8.a.). The DAF COHRP assessor selects this sample from the index of such activities submitted prior to the site visit per paragraph 3.3.h.(21). |
| 4. | Interviews with the institution's HRPP personnel and key stakeholders. This will include observation of HRPP personnel's performance of post-approval compliance monitoring. If the DAF COHRP deems the HRPP's post-approval compliance monitoring processes insufficient, the DAF COHRP may interview the institution's investigators and conduct additional post-approval compliance monitoring. |
| 5. | If the institution has an internal IRB, attendance at a convened IRB meeting. |
| 6. | A final written report to the IO and HRPP personnel with oversight of the activity regarding compliance deficiencies (i.e., from this issuance or its references) and recommendations for improvement. |

**b. (Added)(DAF) Routine periodic audits include review of a sample of institution's HSR review authority determinations. The DAF COHRP selects the sample from the HRPP's index submitted per paragraph 3.3.h.(21). The DAF COHRP will provide institutions at least 20 business days' notice of a request for submission of the sample. The DAF COHRP will generally perform such routine periodic audits remotely. The DAF COHRP notifies the HPD and the relevant HSR review authority regarding the outcome of any routine period audits.**

**c. (Added)(DAF) For DAF institutions with internal IRBs, compliance assessments and routine periodic audits include audits of a sample of the IRB's minutes. The DAF COHRP selects the sample from the list of IRB meetings submitted per paragraph 3.3.h.(21).**

**d. (Added)(DAF) The scope of review necessary to assess compliance of substantive updates to HRPPs (and any associated DoD assurance(s)) may include any processes identified above deemed necessary to ensure compliance of the proposed update.**

**e. (Added)(DAF) Not-for-cause compliance assessments of non-DAF institutions conducting or supporting DAF-conducted or –supported activities that include (or are likely to include) HSR may include one or more processes identified in paragraphs 3.2.a.(3)(a)5.a – c above.**

**f. (Added)(DAF) Performs for-cause compliance assessments of DAF-conducted or supported activities that include (or are likely to include) HSR conducted by DoD or non-DoD institutions. Does so using one or more processes identified in paragraphs 3.2.a.(3)(a)5.a - c above or by other processes deemed necessary. Such assessments will be done with notice, to the extent practical, but the DAF COHRP Director may initiate limited or no-notice compliance assessments, if deemed necessary. Findings of noncompliance during not-for-cause assessments can trigger application of for-cause processes under this paragraph.**

(b) Describe the DoD Component's program or provisions for exercising authorities delegated from the DOHRP to the SDO.

**1. (Added)(DAF) For DAF provisions for exercising such authorities, see the bold "(Added)(DAF)" language which supplements the DoDI 3216.02 in this issuance.**

(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.

**1. (Added)(DAF) The USD(R&E) has granted an exception from the above requirement to obtain DOHRP and SDO (AF/SG) approval in accordance with the paragraph above for such LSGD research determined to be of low or medium risk to national security in accordance with paragraph 3.10.e.(1)(a). For DAF LSGD security review processes, see paragraph 3.10.**

(d) Establish DoD Component and institutional requirements for human subject protection training.

**1. (Added)(DAF) All DAF personnel involved in the conduct, review, or approval of activities which are (or are likely to include) HSR will complete and maintain human subject protection training. (T-0) Document all such training in writing. (T-0) See paragraph 2.5.e for DAF COHRP responsibilities regarding such training.**

**2. (Added)(DAF) For personnel from other DoD Components, DAF accepts human subject protection training certificates documenting compliance with requirements established by the DOHRP and DAF COHRP. Duplicate training is not required.**

(e) Establish procedures for certification in accordance with Part 219 of Title 32, CFR.

**1. (Added)(DAF) DAF procedures for certification are identified in paragraph 2.8.h.(4) (regarding the DAF HRPO). See also paragraph 3.6.b.(6)(a)1.a.**

(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.

**1. (Added)(DAF) For provisions on HPDs, see paragraph 2.7. For provisions on HRPOs and EDOs, see paragraph 2.8.**

(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.

**1. (Added)(DAF) See paragraph 3.3.h.(17).**

(h) Establish DoD Component and institutional responsibilities for required reporting to the DOHRP, including reports pursuant to Title 32, CFR.

**1. (Added)(DAF) See paragraph 2.5.g and paragraph 3.3.h.(21).**

(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.

**1. (Added)(DAF) Personnel will not participate in HSR duties in which they have a prohibited conflict of interest. (T-0)**

**a. (Added)(DAF) The term "conflict of interest" includes any known interest (actual or potential, financial or non-financial) of a person (or of their spouse, dependent child, family member, etc.) that could affect (or reasonably appear to affect) their judgment regarding a separate but related matter.**

**b. (Added)(DAF) "HSR duties" include oversight (e.g., by the IO, HPD, or COHRP) HSR review authority duties, or conduct of HSR.**

**c. (Added)(DAF) Prohibited conflicts of interest include but are not limited to those related to a potential for personal gain, financial gain, or command influence. For example, it is a prohibited conflict of interest to exercise HSR review authorities for activities one conducts or supports (e.g., as a program manager).**

**2. (Added)(DAF) All personnel with HSR duties will disclose to appropriate HRPP leadership (e.g., the HPD) such actual or potential conflicts of interests before performing HSR duties (such as through submission of a completed Office of Government Ethics Form 450 and other relevant facts). (T-1) DAF personnel must also follow applicable Federal regulations and the DoD 5500.07-R, "Joint Ethics Regulation." (T-0)**

**3. (Added)(DAF) HRPP leadership will review the disclosure and ensure the conflicts are either eliminated (e.g., by performance of HSR duties by non-conflicted personnel) or mitigated, as appropriate. (T-0) DAF personnel will identify and manage personal and financial conflicts of interest by DAF personnel.**

(j) Establish policy for the maintenance of HSR records, including records and workflows maintained in electronic form, required by governing regulations and this issuance.

**1. (Added)(DAF) For DAF COHRP requirements, see paragraph 2.5.i. For requirements applicable to DAF institutions, see paragraph 3.3.h.(20).**

(k) Establish policy in accordance with DoDI 6025.23 for addressing subjects' research-related injuries in DoD-conducted research.

**1. (Added)(DAF) See section 3.12.**

(l) Establish policy and institutional requirements for HRPO review of DoD-supported HSR conducted by non-DoD institutions.

**1. (Added)(DAF) See paragraphs 2.8.h and 3.6.**

(m) Establish policy and institutional requirements for administrative review of DoD-supported and DoD-conducted HSR performed by DoD and non-DoD institutions.

**1. (Added)(DAF) See sections 2.8, 3.5, and 3.6.**

b. Required CMP elements may be modified upon waiver request by the COHRP or the prospective COHRP on behalf of the SDO for DOHRP approval.

c. 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.

**(1) (Added)(DAF) The DAF maintains a COHRP and HSR review authorities to implement this CMP. The DAF COHRP Director may request support from other DoD Components to facilitate COHRP functions (e.g., via deferral to their HSR review authorities or acceptance of their HRPP training programs).**

## 3.3. COMMANDERS OR DIRECTORS OF DOD 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:

a. Establish, implement, and maintain an HRPP to ensure the institution's compliance with this issuance.

**(1) (Added)(DAF) A DAF institution must establish and maintain an HRPP if it conducts, supports, or has personnel who serve as HSR review authorities for, activities that include (or are likely to include) HSR. (T-0) Before initiation, the institution must obtain approval of the HRPP, and any substantive changes, from the DAF COHRP Director. (T-1) The waiver authority for each DAF-unique element of the HRPP plan identified in this section is the DAF COHRP Director (unless tiering indicates otherwise).**

**(2) (Added)(DAF) A DAF institution with limited HSR activities (see below) may establish a Limited HRPP in lieu of establishing a full HRPP per paragraph 3.3.h; see Attachment 1. A Limited HRPP will comply with the minimum standards of paragraph 3.3 (i.e., without the DAF supplemental requirements identified in that paragraph by this issuance). (T-0) In addition, Limited HRPPs will designate external HSR review authorities. (T-1) "Limited HSR activities" means rarely (i.e., less than 5 instances per year) doing the following activities:**

**(a) (Added)(DAF) Supporting (but not engaging in) HSR, and/or**

**(b) (Added)(DAF) Conducting exempt HSR per Section 219.104 of Title 32, CFR.**

**(c) (Added)(DAF) Employing DoD-affiliated personnel who conduct HSR while covered under the HRPP (and assurance, if applicable) of another DoD institution (e.g., via execution of an individual investigator agreement (IIA)). While such activity is considered "DoD-conducted HSR," the institution engaged in the HSR is the DoD institution providing IIA coverage (rather than the DoD institution employing the personnel who conduct the HSR under the IIA). The DAF expects the DoD institution providing IIA coverage will include the HSR in the index they provide to the COHRP for the DOHRP in accordance with paragraph 2.2.g.**

b. Provide experienced, well-qualified HRPP staff and appropriate resources needed to ensure compliance with this issuance.

**(1) (Added)(DAF) See paragraph 3.3.h.(5).**

c. Designate an HPD as the primary point of contact for the institution's HRPP.

**(1) (Added)(DAF) See paragraph 3.3.h.(5)(a).**

d. As applicable, identify an IO to establish and maintain a DoD assurance and other appropriate assurances. An alternate IO (AIO) may be appointed.

**(1) (Added)(DAF) Will either serve as the institution's IO or will identify and appoint an appropriate senior leader to serve as the IO. (T-0) See paragraphs 3.4.a.(1)(b), 3.3.h.(4), and Glossary, G.2., Definitions.**

**(2) (Added)(DAF) May appoint alternate IOs (AIOs) with authority to act on behalf of the institution for the purposes of the HRPP; any such appointment will be in writing. (T-1) Regardless of appointment of an IO, the commander (or equivalent), as the most senior official of the institution, remains responsible for the institution's compliance. See also paragraph 3.3. If the IO appoints an AIO, the HRPP plan will identify which IO roles and responsibilities the AIO is authorized to perform, with the following exceptions.**

**(a) (Added)(DAF) The IO will be the signatory official for initial submission and renewal of the institution's HRPP and any assurance(s). (T-1)**

**(b) (Added)(DAF) The IO will complete training required by the DAF COHRP. (T-0)**

**(c) (Added)(DAF) The DAF COHRP Director, institutional personnel (e.g., the HPD), and DoD HSR review authorities upon which the institution relies will have access to the IO to discuss important issues of concern to the HRPP (e.g., regarding potential undue influence). (T-1) Note: Access may require preliminary discussions with the AIO, who may be able to resolve the issues at a less senior level.**

e. Evaluate and improve the institution's HRPP, its policies, and its standard operating procedures.

**(1) (Added)(DAF) See paragraph 3.3.h.(7).**

f. Establish a program of post-approval compliance monitoring of HSR conducted or supported by the institution.

**(1) (Added)(DAF) See paragraph 3.3.h.(7).**

**g. (Added)(DAF) Provide an environment that strives to ensure compliance and ethical treatment of human subjects, while reducing the possibility for conflict of interest by personnel responsible for protecting human subjects.**

**h. (Added)(DAF) Implement and maintain an HRPP plan to ensure the institution complies with DoD policies for protection of human subjects per paragraph 1.2 and all other requirements herein. (T-0) Ensure the HRPP plan includes the following elements:**

**(1) (Added)(DAF) A statement of principles to ensure the HRPP is established, implemented, and maintained in accordance with this issuance. (T-0) Begin with a statement of the ethical framework applicable to all research the institution supports, conducts, or for which the institution provides HSR review authorities. (T-0)**

**(2) (Added)(DAF) If the institution will <u>conduct</u> activities which include (or are likely to include) HSR, procedures to comply with paragraphs 3.4 (regarding assurances), and 3.5 (regarding DoD-conducted research). (T-0)**

**(3) (Added)(DAF) If the institution will <u>support</u> activities which include (or are likely to include) HSR and which are conducted by non-DoD institutions, procedures to ensure compliance with paragraphs 3.6 (regarding DoD-supported research) and 3.7 (regarding DoD-assisted research).**

**(4) (Added)(DAF) Procedures to identify and maintain an IO and, if necessary, an AIO, per paragraph 3.3.d. (T-0)**

**(5) (Added)(DAF) Procedures to provide experienced, well-qualified HRPP personnel and resources needed to ensure compliance with this issuance. (T-0) This will include provisions for written IO designation of the following HRPP functions.**

**(a) (Added)(DAF) An HPD (see paragraph 2.7). (T-0) If the HPD conducts HSR at their institution, to avoid a conflict of interest, identify an alternate HPD (i.e., who does not conduct the HPD's HSR) to perform HPD functions for the HPD's HSR.**

**(b) (Added)(DAF) As needed to oversee the institution's activities, designation of personnel to serve as HSR review authorities as described in Table 1. (T-0)**

**1. (Added)(DAF) Include provisions for designation of internal HSR review authorities (see Table 1) (i.e., performed by the institution). (T-0) Such designation should be effective only during employment, unless withdrawn sooner.**

**2. (Added)(DAF) Include provisions for designation of external HSR review authorities (see Table 1) (i.e., those performed by another institution, such as a under a reliance agreement). This will include provisions both for routine reliance and for deferral to avoid duplicate HSR review authority determinations. DAF institutions with HRPPs which document reliance on external HSR review authorities will abide by the external HSR review authorities' HRPP plan(s) with regards to the provided services. (T-3) This will be in lieu of executing a separate agreement (such as an institutional agreement for IRB review (IAIR)) and following separate HRPP plan policies and procedures.**

**3. (Added)(DAF) If the institution plans to rely on more than one DoD IRB, provide guidance regarding how to appropriately select the DoD IRB for each study, as applicable. Include provisions for use of a single IRB per paragraph 1.2.j. (T-0)**

**(6) (Added)(DAF) Procedures for each research review type anticipated to be performed by the institution. If applicable, include provisions regarding any delegations of authority from the DAF COHRP (e.g., CLAR authority). Include the following:**

**(a) (Added)(DAF) Ensure the HSR review authority functions' procedures comply with both the portions of this issuance specific to each function (see Table 1) and other requirements of this issuance, as applicable. (T-1)**

**(b) (Added)(DAF) If the institution maintains an internal IRB, include procedures to ensure its compliant administration, e.g.:**

**1. (Added)(DAF) Management of IRB operations, to include IRB function and operation requirements of Part 219, Title 32, CFR, and this issuance. (T-0) See also paragraph 2.8.g. (on the IRB chair) and paragraphs 3.5 (on DoD-conducted research) and 3.6.b.(5) (on non-DoD conducted research reviewed by a DoD IRB).**

**2. (Added)(DAF) Written IO approval of IRB membership, to be provided to each IRB member. (T-1) To ensure there is no appearance of undue influence, the IO and AIO(s) will not serve as members of their institution's IRB. (T-1)**

**3. (Added)(DAF) Coordination of IRB meetings; generation and tracking of related correspondence; and dissemination of determinations in a timely manner.**

**4. (Added)(DAF) Means to ensure the IRB chair and IO remain informed of updates to requirements and other events affecting the HRPP.**

**5. (Added)(DAF) In addition to IRB membership requirements established by Part 219, Title 32, CFR, if a DAF IRB reviews medical research or non-medical research with a**

**medical risk to human subjects, include one or more appropriately trained medical professionals as either IRB members or non-voting expert consultants. (T-3)**

**6. (Added)(DAF) Provisions to suspend and terminate IRB approval of research when necessary to ensure protection of human subjects. (T-0)**

**(c) (Added)(DAF) If the institution maintains an internal HRPO, include provisions for certification (i.e., official notification by the non-DoD institution to the supporting DAF institution that HSR has been reviewed and approved by an IRB in accordance with an approved assurance).**

**(7) (Added)(DAF) Processes to ensure continual evaluation and quality improvement of the DAF institution's HRPP. (T-0) Include procedures for HPD assessment of the HRPP plan (and associated documentation) at appropriate intervals to ensure it remains current, compliant, and effective.**

**(a) (Added)(DAF) Include processes to monitor the institution's activities to determine whether personnel are conducting or supporting activities which include (or are likely to include) HSR. (T-1) Such personnel may include directors; program managers or officers; contracting or agreements officers; test and evaluation personnel; safety personnel; technical points of contact; and others responsible for such activities. In order to accurately assess whether an activity might include HSR, such personnel should either complete HRPP training or consult with a HSR review authority (see Table 1) with purview over the activities. Personnel are not authorized to make human research determinations for their own activities.**

**(b) (Added)(DAF) Include processes for compliance assessments (both for-cause and not-for-cause) of the institution's HRPP activities. (T-0) "HRPP activities" include any HSR the institution conducts or supports, as well as any research reviews the institution provides in accordance with paragraph 2.8.**

**1. (Added)(DAF) Include post approval compliance monitoring of a representative sample of HSR by qualified personnel at appropriate intervals (at least annually). This should include site visits (in person or remote, as appropriate) to HSR locations (e.g., to observe the consent process, if appropriate) and interviews (e.g., with research investigators, key research staff). This should also include review of HSR records to confirm subject eligibility, compliance with any IRB approved protocol, and proper execution of signed informed consent documents.**

**2. (Added)(DAF) Include routine audits (such as by the HPD) of a sample of reviews performed by the institution's HSR review authorities, as applicable. (T-1)**

**3. (Added)(DAF) Include provisions to ensure the IO, HPD, and other HRPP personnel, as appropriate, review any required reports in a timely manner and take appropriate actions to improve the HRPP, as needed.**

**4. (Added)(DAF) Include provisions to facilitate DAF COHRP compliance assessments of the HRPP in accordance with paragraph 3.2.a.(3)(a).**

**(8) (Added)(DAF) Processes to ensure implementation of appropriate protections when personnel affiliated with the institution are sought for involvement as human subjects in research (see paragraph 3.9.f). (T-1)**

**(9) (Added)(DAF) Procedures for appropriate management of conflicts of interest in accordance with paragraph 3.2.a.(3)(i).**

**(10) (Added)(DAF) Procedures to ensure personnel have human subject protection training commensurate to their roles before becoming involved in, and throughout, the following activities: conducting HSR, supporting HSR, or performing research reviews per Table 1. (T-0) Roles which require such training include but are not limited to the institution's IO, AIO, HPD, HSR review authorities, research investigators, and key research personnel. (T-0)**

**(11) (Added)(DAF) Provisions for outreach efforts to ensure institution-wide awareness of and compliance with this issuance and the HRPP (e.g., through a communications plan facilitated by IO engagement). (T-0) This will include dissemination of information about HRPP requirements for prior review of activities that are likely to include HSR, and identification of any authorized EDOs, HRPOs, and/or IRBs. (T-1)**

**(12) (Added)(DAF) Procedures regarding protection of human subjects from medical expenses, if injured, in compliance with paragraph 3.12.**

**(13) (Added)(DAF) Procedures regarding any of the following types of HSR the institution may conduct or support:**

**(a) (Added)(DAF) For classified HSR, include provisions for compliance with paragraph 3.13 (e.g., to ensure successful review by the DOHRP prior to start), including engagement of HSR review authorities (e.g., an IRB) with the appropriate security clearance level for the HSR. (T-0)**

**(b) (Added)(DAF) For research involving LSGD collected on DoD-affiliated personnel, include provisions for compliance with paragraph 3.10.**

**(c) (Added)(DAF) For HSR involving biosafety and biosecurity requirements, include provisions for compliance with paragraph 1.2.e.**

**(d) (Added)(DAF) For HSR conducted in a foreign country, include relevant provisions as stated throughout this issuance, such as in paragraphs 3.5.b and 3.6.a.**

**(14) (Added)(DAF) Provisions to ensure investigators promptly and thoroughly address requirements issued by HSR review authorities in accordance with the HRPP.**

**(15) (Added)(DAF) Processes to ensure HSR proposed to be conducted or supported by the institution is vetted by institutional leadership before initiation, as follows. (T-0)**

**(a) (Added)(DAF) DAF personnel will only conduct HSR after it has been approved by their IO or other senior institutional official (i.e., as stated in the institution's HRPP plan). (T-1) The purpose of this review is to determine whether to permit the HSR, e.g. in light of local mission**

**considerations. This review can be done before or after IRB approval, and is not part of the IRB review process.**

**(b) (Added)(DAF) Investigators must obtain prior written approval from command or Component leadership to either: involve DoD-affiliated personnel (including their identifiable records or biospecimens) as human subjects in research or conduct HSR on a DoD facility. (T-0) See paragraphs 3.5.a.(6) and 3.9.f.(2). Researchers will follow applicable requirement to obtain such approval. (T-1)**

**(16) (Added)(DAF) A process to ensure the institution only conducts HSR which has been determined to have scientific merit. (T-0 for non-exempt HSR; T-3 for exempt HSR) Include provisions to confirm its consideration by the IRB before approving non-exempt HSR. (T-0) Include consideration of feasibility of study completion per paragraph 3.5.a.(5). (T-3)**

**(17) (Added)(DAF) Procedures for the institution to ensure allegations of noncompliance involving the institution are promptly documented, investigated, resolved, and reported as required by paragraphs 3.2.a.(3)(a)5. and 3.16. Such procedures will include determinations regarding whether substantiated noncompliance involving HSR constitutes serious or continuing noncompliance as defined by this issuance.**

**(18) (Added)(DAF) Provisions to ensure continuity of operations. See also paragraph 3.17.**

**(19) (Added)(DAF) Provisions to ensure compliance with AFI 33-332, "Air Force Privacy and Civil Liberties Program," and AFI 41-200, "Health Insurance Portability and Accountability Act (HIPAA)," when applicable to HSR. For example, DAF IRBs seeking to serve as Privacy Boards will comply with the requirements of DoD Manual 6025.18.**

**(20) (Added)(DAF) Processes to maintain HRPP records, e.g., records of HSR the institution conducts (e.g., such as informed consent documents), supports, or for which it performs research reviews in accordance with paragraph 3.15. (T-0)**

**(21) (Added)(DAF) Procedures to ensure prompt reporting of all items which require review by the DAF COHRP or other higher-level authorities per this issuance (e.g., paragraphs 3.1 (reports) and 3.13 (classified HSR)). (T-0) Include an executive summary and supporting documentation in sufficient detail to facilitate applicable reporting requirements. The DAF COHRP sends the reports to the DOHRP.**

**(a) (Added)(DAF) Procedures to ensure the institution does not permit initiation of any activities (e.g., by release of approval) prior to successful completion of any required higher-level review or CLAR. (T-0)**

**(b) (Added)(DAF) Procedures to compile the index of all HSR the institution conducted, supported, or reviewed (through their HSR review authorities) in accordance with paragraph 2.2.g.**

**1. (Added)(DAF) For each such HSR protocol, include in the index: protocol number(s); protocol title; key investigator name; key investigator institution; type of study (exempt or non-exempt); the institution's role in the HSR (conducting, supporting, and/or**

**reviewing in accordance with Table 1); the name of the institution providing the research review(s) for the HSR (see Table 1); date of initial determination; approximate level of funding (if available); name of all supporting DoD institutions (if available); and, if applicable, date of protocol closure. (T-1)**

**2. Each DAF HPD will provide to the COHRP their institution's index of all their conducted or supported HSR. (T-0) To ensure timely submission to the DOHRP by the end of each fiscal year, DAF institutions will submit the index to the DAF COHRP annually by 1 September. The DAF COHRP will compile and submit the above index to the DOHRP. (T-0)**

**(c) (Added)(DAF) To facilitate oversight of the DAF institution's HRPP per paragraph 3.2.a.(3)(a), processes to submit to the DAF COHRP, on a yearly basis and prior to their compliance assessment (routine or for- cause):**

**1. (Added)(DAF) Updates to the index of HSR described above. (T-3)**

**2. (Added)(DAF) If the institution maintains an internal IRB, a list of IRB members and all dates of IRB meetings conducted since submission of the last report. (T-1)**

**3. (Added)(DAF) A list of activities determined by the institution's EDO(s) or IRB not to be research or involve human subjects. (T-1)**

**4. (Added)(DAF) On request, electronic copies of a sample of the HSR review authority determinations made by the institution's personnel, with supporting documentation. (T-1)**

**(22) (Added)(DAF) Information security program processes regarding appropriate access control and other protective measures for safeguarding research data in accordance with DoDM5200.01V1_AFMAN16-1404V1, "Information Security Program: Overview, Classification, and Declassification," and DoDI5200.48_DAFI16-1403, "Controlled Unclassified Information (CUI)."**

**i. (Added)(DAF) Include in their test and evaluation guidance (required per DoDI5000.89_DAFI99-103, "Capabilities-Based Test and Evaluation") procedures for assessing whether activities include (or are likely to include) human research prior to any test event. (T-1) All procedures for such human research assessments must comply with this issuance, including the requirement for DAF COHRP approval of such procedures prior to implementation. (T-1)**

## 3.4. FEDERAL ASSURANCE.

### a. When a Federal Assurance Is Required.

(1) A DoD institution conducting non-exempt HSR must have a DoD assurance for the protection of human subjects. All DoD assurances must be executed using templates approved by the DOHRP. Regional or multi-site DoD assurances are allowed as long as they are reasonable and can be overseen adequately; these must be approved by the DOHRP.

**(a) (Added)(DAF) Before their personnel conduct non-exempt HSR, each DAF institution must obtain either DAF COHRP Director approval of their DoD assurance or coverage of such personnel under another institution's DoD assurance through execution of an IIA. (T-0)**

**1. (Added)(DAF) DAF personnel covered by an IIA will submit a copy to their institution's HPD, if any. (T-3) If the DAF personnel covered by the IIA do not have an HPD and the IIA provides coverage under another DoD Component's assurance, provide a copy of the IIA to the DAF COHRP Director. (T-3)**

**2. (Added)(DAF) DAF institutions can obtain the DoD assurance template by contacting the DAF COHRP through their organizational e-mail box: usaf.pentagon.af-sg.mbx.afmsa-sge-c@health.mil.**

**(b) (Added)(DAF) Define the institution (i.e., in the HRPP and, if applicable, the DoD assurance) at the most senior level appropriate to ensure command-level oversight to allow IO (and AIO) awareness of the institution's HRPP and research activities.**

(2) A DoD institution must have a Department of Health and Human Services (HHS) assurance, also known as a federal-wide assurance (FWA), when conducting non-exempt HSR supported by HHS.

(3) A non-DoD institution must rely on an FWA, or a comparable federal assurance, when engaged in non-exempt DoD-supported HSR.

**(a) (Added)(DAF) Note: The above requirement to rely on an FWA also applies to research conducted by a foreign (i.e., non-U.S.) non-DoD institution.**

(4) Researchers affiliated with institutions that do not hold a federal assurance may enter into individual investigator agreements (IIA) to associate with an institution with a federal assurance. All researchers conducting non-exempt HSR must be covered by their own institution's federal assurance or by another institution's federal assurance through an IIA.

(5) All institutions with a DoD assurance must identify at least one IRB on their DoD assurance, and must list all DoD IRBs operated by their institution, as well as agreements for IRB support.

(6) An institution with a DoD assurance must, on its assurance(s), identify the IO as the senior individual authorized to represent the institution; establish and be responsible for the institution's HRPP; and identify the HPD as the primary contact for the institution's HRPP.

(7) DoD institutions and all non-DoD institutions conducting HSR that receive support from the DoD must comply with the terms of their federal assurances, if they hold one, this issuance, and relevant policies of the cognizant DoD Component.

### b. When a Federal Assurance Is Not Required.

(1) A federal assurance is not required when an institution's role is limited to the conduct or support of exempt HSR or activities determined by designated HRPP personnel to be research not involving human subjects.

(2) DoD institutions that only support HSR conducted by an institution with an assurance, also known as an assured institution, are not required to maintain their own federal assurance.

## 3.5. DOD-CONDUCTED RESEARCH.

### a. DoD Institutional Approval and Oversight.

(1) DoD institutions must have policies and procedures to ensure that all applicable HSR approvals are in place before HSR begins.

(2) A DoD IO or AIO, on behalf of their institution, may enter into an agreement to rely on another DoD institution's IRB without executing an Institutional Agreement for IRB Review (IAIR) because both institutions rely on DoD assurances that delineate the responsibilities of the reviewing and relying DoD IRBs.

(3) A DoD IO or AIO, on behalf of their institution, may establish an agreement for IRB support with an institution that does not hold a federal assurance. This agreement is not an IAIR; rather it is an agreement between an assured institution and a non-assured institution providing IRB services. The agreement must specify that the IRB must apply the requirements in this issuance for DoD-conducted research. The DoD IO and AIO must be given approval by the COHRP, on behalf of the SDO, to have the ability to establish such agreements.

**(a) (Added)(DAF) Each DAF institution seeking to rely on a non-DoD IRB for review of DAF-conducted activities per the paragraph above will include in its HRPP plan procedures to ensure compliance with the requirements of paragraphs 3.5.a.(8)(b), (c), and (e).**

(4) DoD IRBs must comply with Section 219.107 of Title 32, CFR.

(5) DoD IRBs will document their consideration of scientific merit; within the consideration of scientific merit, feasibility of study completion should be considered.

(6) If the HSR involves DoD-affiliated personnel, the key investigator must receive approval from the DoD-affiliated personnel's command or DoD Component to conduct the research. If the HSR takes place on a DoD facility, the key investigator must also receive approval from the command or DoD Component responsible for the facility.

**(a) (Added)(DAF) See also paragraph 3.9.f.**

(7) Only designated federal DoD HRPP personnel are authorized to make determinations regarding whether or not an activity is HSR or is exempt HSR.

**(a) (Added)(DAF) DAF designates only IRBs (including IRB members designated to perform this function by the IRB chair) and EDOs to make official determinations per Sections 219.102 and .104 of Title 32, CFR for DAF-conducted activities that may include HSR, or that are exempt HSR (see Glossary) per Section 219.102 of Title 32, CFR.**

**1. (Added)(DAF) For EDO and IRB determinations:**

**a. (Added)(DAF) Cite any specific human research protection regulatory determinations made and include a brief written justification for each.**

**b. (Added)(DAF) Provide a brief written justification for any disapproval or condition of approval.**

**2. (Added)(DAF) EDOs will comply with the following special considerations:**

**a. (Added)(DAF) When an activity requires limited IRB review per Sections 219.104 and 219.111 of Title 32, CFR, the reviewing EDO must refer the activity to a DoD IRB for the final determination. (T-0)**

**b. (Added)(DAF) When an activity involves secondary research use of certain identifiable health information per paragraph 219.104(d)(4)(iii) of Title 32, CFR, the reviewing EDO must refer the activity to a DoD IRB or DoD Privacy Board for the final determination per DoD Manual 6025.18, "Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs."**

**c. (Added)(DAF) When an activity involves use of broad consent in accordance with Part 219 of Title 32, CFR, paragraph 104(d)(7) and (8), see paragraph 1.2.i.**

**(b) (Added)(DAF) For DAF-conducted collaborative activities involving other DoD Components that may include HSR, the DAF should defer to HSR review authority determinations made by other DoD Components.**

(8) DoD institutions collaborating in HSR with non-DoD institutions may rely on the collaborating non-DoD institution's IRB if all of the following conditions are met:

(a) The DoD institution determines the non-DoD institution has an appropriate federal assurance or that a federal assurance is not required.

(b) The non-DoD institution's IRB is registered in accordance with Subpart E of Part 46 of Title 45, CFR.

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

**1. (Added)(DAF) The compliance review required by the paragraph above must be performed by a DAF IRB chair (or their IRB member designee(s)), a DAF HRPO, or a DAF CLAR official. (T-3) Exception: The DAF COHRP Director has authority to approve designation of an alternative DoD HSR review authority to perform the compliance review required by this paragraph.**

(d) The DoD institution and the non-DoD institution (including if the non-DoD institution uses an independent IRB) enter into an IAIR specifying that the non-DoD IRB will apply the DoD requirements specified in this issuance.

**1. (Added)(DAF) Submit to the DAF COHRP all IAIRs (or similar agreements) involving DAF institutions (i.e., as either the institution relying on the IRB services or the institution supplying the IRB services). (T-0)**

**2. (Added)(DAF) Upon submission of the IAIR to the DAF COHRP, a DAF institution's DoD assurance is considered updated to include any additional IRBs supplying IRB services to the DAF institution.**

(e) If the research constitutes classified HSR, the COHRP, on behalf of the SDO, approves the agreement to rely on the non-DoD institution's IRB.

(9) DoD institutions conducting HSR in collaboration with non-DoD institutions with or without DoD support must comply with all requirements in this issuance pertaining to DoD-conducted research.

### b. DoD Component Administrative Review and Oversight.

(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.

**1. (Added)(DAF) Submit to the CLAR official (the DAF COHRP or their designee) documentation that the IRB approved the research in light of each of the following requirements of paragraph 1.2.f and Part 219 of Title 32, CFR.**

**a. (Added)(DAF) The IRB confirmed the HSR is compliant with applicable laws and requirements of each foreign country where it will be conducted. (T-0)**

**b. (Added)(DAF) The IRB considered knowledge of the local research context, including cultural sensitivities, before approving participation of foreign research subjects in the foreign country(ies). (T-0)**

**2. (Added)(DAF) The IRB must document the source of information about the foreign research context in writing and maintain this with the research records (e.g., via letters from consultants and/or IRB minutes of meeting discussions in which consultants participated). (T-0) Consultants participating in IRB meetings may not vote unless they are IRB members qualified to vote. (T-0)**

(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.

**1. (Added)(DAF) The DAF COHRP will coordinate any required DOHRP review after CLAR approval is issued. (T-1) The DAF COHRP will courtesy copy the conducting DoD institution on the submission to the DOHRP. (T-3)**

**(g) (Added)(DAF) The research involves biological or chemical warfare agents or weapons and is not prohibited by 50 U.S.C. 1520a. (T-0)**

**(h) (Added)(DAF) The activity is either exempt HSR (per Section 219.104 of Title 32, CFR) or non-exempt HSR, *and* involves collection of statistical information under a promise of confidentiality pursuant to Sections 501-513 of the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) (Public Law 107-347). (T-1) See also paragraph 3.14.a.**

(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) (Added)(DAF) See paragraph 2.8.i.**

## 3.6. DOD-SUPPORTED RESEARCH.

### a. DoD Component Approval and Oversight.

(1) The DoD Component must conduct a CLAR of all non-exempt HSR when any of the following conditions occur:

(a) Research is conducted in a foreign country, unless it is conducted by a DoD overseas institution, or involves subjects who are DoD-affiliated personnel that are U.S. citizens.

(b) The research requires a waiver of informed consent pursuant to Paragraph (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.

**1. (Added)(DAF) The DAF COHRP will coordinate any required DOHRP review after CLAR approval is issued. (T-1) The DAF COHRP will courtesy copy the conducting DoD institution on the submission to the DOHRP. (T-3)**

**(g) (Added)(DAF) The research involves biological or chemical warfare agents or weapons and is not prohibited by 50 U.S.C. 1520a. (T-0)**

**(h) (Added)(DAF) The activity is either exempt (per Section 219.104 of Title 32, CFR) or non-exempt HSR, and involves collection of statistical information under a promise of confidentiality pursuant to Sections 501-513 of CIPSEA (Public Law 107-347). (T-1) See also paragraph 3.14.a.**

(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 DoD Component review and oversight of Sections 3.5.b.(1)(a) - (f) to a DoD institution.

**(a) (Added)(DAF) See paragraph 2.8.i.**

**(4) (Added)(DAF) For HRPO or CLAR determinations, provide a brief written justification for any disapproval or condition of approval. CLAR is conducted either concurrent with or after HRPO review.**

### b. DoD Institutional Approval and Oversight.

DoD institutions planning to support HSR must comply with the requirements in this paragraph, as applicable.

(1) Support for activities including research involving human subjects must consider Defense Federal Acquisition Regulation Supplement (DFARS) Section 207.172 requirements as part of the acquisition planning process. 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.

**1. (Added)(DAF) DAF personnel responsible for authorizing solicitations and awards for activities which may include support to HSR will take one of the following actions with respect to determining whether to include the above-referenced DFARS clause (or similar language) in solicitations. (T-1)**

**a. (Added)(DAF) Include in the solicitation or award the above-referenced DFARS clause (or similar language, as appropriate) and ensure HRPO review is conducted prior to initiation.**

**b. (Added)(DAF) Complete appropriate human research protection training (e.g., established by their HRPP or the DAF COHRP) to assess whether the activity might include HSR; if it may, then include the above-referenced DFARS clause.**

**c. (Added)(DAF) Consult with a HSR review authority before determining it is appropriate to omit the above-referenced DFARS clause.**

(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.

(2) 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.

(3) DoD institutions must appoint or designate HRPO(s) to confirm that DoD-supported HSR complies with this issuance.

**(a) (Added)(DAF) Successful completion of HRPO review is required prior to initiation of DAF supported activities which include (or are likely to include) HSR. Submit all required paperwork for contracts, grants, and other awards to enable HRPO review. Prior to initiation of the research, the non-DoD institution will ensure the HRPO has completed their review by issuing their "concurrence." (T-0) See also paragraph 3.6.a, regarding an additional administrative review (i.e., CLAR) required for certain types of research.**

**(b) (Added)(DAF) DAF government officials responsible for provision of support to non-DoD institutions for the performance of activities that include (or are likely to include) HSR will:**

**1. (Added)(DAF) Ensure appropriate information is included in solicitations, awards, and agreements, as required by paragraph 3.6.b. (T-0) This will include provision of contact information for the HRPO at the time of solicitation, the award, or soon after award. (T-0)**

**2. (Added)(DAF) Provide to the HRPO contact information for the DAF government officials responsible for provision of support to the activities. (T-3) Promptly notify the HRPO of any changes to this information. (T-3)**

(4) 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.

**(a) (Added)(DAF) The DAF COHRP recommends inclusion of the DFARS clause or similar language in agreements to provide DoD support to another Federal department or agency for activities that could include HSR, *and* when the Federal department or agency does not plan to conduct the HSR. In light of the limited involvement provided by the Federal department or agency here, DoD HRPO oversight should be viewed as an important tool to help ensure compliance.**

(5) When a DoD IRB serves as the reviewing IRB pursuant to Part 219 of Title 32, CFR, the DoD IRB approval will constitute the HRPO review; an additional HRPO review is not required.

**(a) (Added)(DAF) A determination by a DoD EDO or DoD IRB that a non-DoD conducted activity is not HSR or is exempt HSR will constitute the HRPO review. An additional HRPO review is not required.**

(6) The non-DoD institution:

(a) 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.

**a. (Added)(DAF) Submission of the above documentation to the HRPO constitutes "certification" as defined in the Glossary. See also paragraph 2.8.h.**

**b. (Added)(DAF) Include all final approved versions of materials the IRB reviewed for the activity (e.g., any data collection tools, advertisements, informed consent documents, subject information sheets, etc.).**

**c. (Added)(DAF) Include documentation of any special determination of the IRB made for the activity. Examples include but are not limited to the following, as applicable. Include documentation on any waivers approved in accordance with sections 219.116(e) and (f) (waiver or alteration of consent) or 219.117(c) (waiver of the requirement to document signed consent) of Title 32, CFR. Include documentation for any determinations regarding additional protections needed in accordance with paragraph 3.9. Include information required to document compliance of HSR conducted in a foreign country per paragraph 3.6.b.(6)(f).**

**d. (Added)(DAF) If the activity includes artificial intelligence (AI), submit to the HRPO documentation required by paragraph 3.19.**

2. Documentation of key investigators' human research protection training.

3. IRB-approved protocol documents.

4. Current FWA and IRB registration numbers.

**5. (Added)(DAF) Written documentation of institutional approval from each engaged DoD institution (documented in accordance with each institution's HRPP). See also paragraph 3.3.h.(15)**

**6. (Added)(DAF) If the HSR involves DoD-affiliated personnel or facilities, documentation of command or Component approval to execute the research in accordance with paragraphs 3.5.a.(6) and 3.9.f.(2). (T-0) Note: For phased research, investigators may be able to negotiate timing of submission of this documentation to the HRPO, but it must be received in time to allow completion of the required HSR review authority determination (e.g., by the HRPO) before the HSR begins. (T-0)**

**7. (Added)(DAF) The statement of work. (T-0)**

**8. (Added)(DAF) As applicable, any related IIAs, IAIRs, or similar agreements. (T-1)**

(b) 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.

**1. (Added)(DAF) The intent of the above paragraph is only to require submission of such documentation for research which includes (or is likely to include) either human subjects or LSGD collected from DoD-affiliated personnel, in accordance with paragraph 3.6.b.(1).**

**2. (Added)(DAF) For the purposes of compliance with the above paragraph, "all protocol documents" includes the final version of the materials the HSR review authority reviewed for the activity and the statement of work. (T-3) This should include a written justification for the IRB's (or similar HSR review authority) determination supported by facts and regulatory citations (e.g., applicable exempt category per Section 219.104 of Title 32, CFR, or applicable category from the DoDI 3216.02). Note: The Glossary defines activities that are not research (see definition of "research") and are excluded from the definition of HSR (see "excluded activities").**

**3. (Added)(DAF) For exempt HSR (including that which requires limited IRB review), provide the additional documentation described in this paragraph. If the HSR involves DoD-affiliated personnel or facilities, include documentation of command or Component approval in accordance with paragraphs 3.5.a.(6) and 3.9.f.(2). (T-0) Include documentation of key investigators' human research protection training. (T-3) If the HSR will involve interactions or interventions with human subjects, provide documentation of consideration of the Belmont Report requirement to obtain informed consent (such as through submission of an information sheet for human subjects). (T-0)**

**4. (Added)(DAF) For all such HSR conducted in a foreign country, see also paragraph 3.6.b.(6)(f).**

**5. (Added)(DAF) If the activity includes artificial intelligence (AI), submit to the HRPO documentation required by paragraph 3.19.**

(c) Must comply with all reporting requirements that may otherwise be applicable, in addition to the HRPO reporting and submission requirements in this section.

(d) 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.

**a. (Added)(DAF) The non-DoD institution will promptly submit to the HRPO any reports required by paragraph 3.1 related to any DoD-supported HSR conducted by the non-DoD institution. (T-0)**

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.

**e. (Added)(DAF) Wholly or partially terminating or suspending any other DoD support.**

11. Will recognize that DoD-supported research should comply with the whole of this issuance when applicable.

**(e) (Added)(DAF) For the following types of DoD-supported activities, must submit institutional documentation of this determination to the HRPO, to include all activity documents (e.g., written operational plans).**

**1. (Added)(DAF) Those determined by a non-DoD institution to be "authorized operational activities" as defined in the Glossary. (T-3)**

**2. (Added)(DAF) Those determined by a non-DoD institution to be "operational test and evaluation" as defined Section 139(a)(2)(A) of Title 10, U.S.C. (T-3)**

**3. (Added)(DAF) Those determined by a non-DoD institution to fall under the last paragraph of the definition of "excluded activities" as defined in the Glossary (i.e., "Activities, including program evaluation and surveys…"). (T-3)**

**(f) (Added)(DAF) For all HSR (exempt or non-exempt) conducted in a foreign country, submit to the HRPO documentation the IRB approved the research in compliance with each of the following requirements of paragraph 1.2.f and Part 219 of Title 32, CFR.**

**1. (Added)(DAF) The IRB confirmed the HSR is compliant with applicable laws and other requirements of the foreign country(ies) where it will be conducted. (T-0)**

**2. (Added)(DAF) The IRB considered knowledge of the local research context, including cultural sensitivities, before approving participation of foreign research subjects in the foreign country(ies). (T-0)**

**(g) (Added)(DAF) For DoD-supported activities with a "substantive change" (see Glossary), must submit appropriate documentation to the HRPO for review and approval prior to initiation. (T-1) To determine necessary documentation, see paragraph 3.6.b.(6).**

## 3.7. DOD-ASSISTED RESEARCH.

Each COHRP must establish policy to oversee the DoD Component's execution of DoD-assisted research, or delegate the responsibility to create such policy to the DoD Component's institutions. To the extent consistent with this issuance, a DoD Component may waive some procedures applicable to DoD-supported HSR when the DoD support is limited to assistance (as defined in this issuance).

**a. (Added)(DAF) Per the definition of "support," only non-DoD conducted HSR is considered DoD-assisted, and assistance is a subset of support. A common example of DoD-assisted HSR is research conducted by DoD or non-DoD personnel pursuing academic degrees at non-DoD institutions with DoD permission to recruit DoD personnel as subjects on base. DoD-assisted HSR is not considered a DAF official mission.**

**b. (Added)(DAF) DAF assistance to HSR triggers applicability of additional requirements, such as the DoD-unique human research protection considerations identified in this issuance. The HSR review authority requirements applicable to DoD-assisted research are referenced below.**

**(1) (Added)(DAF) All DAF-supported HSR, including the subset limited to assistance, must comply with the HSR review authority requirements of paragraph 3.6. (T-3)**

**(2) (Added)(DAF) If a DAF command or Component approves their personnel to conduct DoD-assisted HSR (e.g., a student project for a non-DoD school) while on duty time, the HSR review authority must determine whether this portion of the research constitutes "DoD-conducted HSR" as defined in the Glossary. If so, this triggers applicability of additional requirements for DoD-conducted HSR. If the HSR will be both DoD-conducted (i.e., conducted while on-duty) and non-DoD conducted (i.e., conducted while off-duty), it must then comply with the HSR review authority requirements of paragraph 3.5 (for DoD-conducted HSR) in addition to 3.6 (for DoD-supported HSR). (T-0)**

**(3) (Added) (DAF) DAF HSR review authorities (whose determinations are required before DAF provides assistance) must prioritize review of DAF official mission activities. (T-3)**

**c. (Added)(DAF) DAF commanders requested to approve provision of assistance to non-DoD conducted HSR (that is not otherwise DoD-conducted or -supported):**

**(1) (Added)(DAF) Will determine whether to approve such requests in light of applicable mission requirements (e.g., would participation affect personnel ability to mobilize for readiness, to perform duties, or to be available for duty). (T-1) Will disapprove such requests for DoD assistance to non-DoD conducted HSR if the assistance will adversely affect performance of official DoD duties. When disapproving requests for DoD assistance, may identify potential alternatives, such as recruitment through non-governmental entities or use of Freedom of Information Act requests.**

**(2) (Added)(DAF) Will only provide assistance to HSR to the extent this is determined to be permissible in accordance with DoD 5500.07-R (e.g., regarding use of public office for private gain and criteria which must be met before Federal Government resources can be permitted for non-official purposes). (T-0) Must document this determination in the command or Component approval documentation approving the assistance. (T-1)**

**(3) (Added)(DAF) Will only approve their personnel to conduct their DAF-assisted HSR while on duty after the commander establishes a human research protection program (HRPP) in accordance with paragraph 3.3.h. Note: A DAF institution with HSR activities limited to provision of assistance as defined herein may establish a limited HRPP per paragraph 3.3.a.(2) (in lieu of establishing a full HRPP per paragraph 3.3.h).**

**d. (Added)(DAF) The DAF COHRP is authorized to waive DAF-unique HRPO requirements (see DAF supplements in paragraph 3.6) for DoD-assisted research. To request such a waiver, include the proposed HRPO procedures in an updated HRPP plan and submit this to the HRPO with the DAF Form 679, "Department of the Air Force Publication Compliance Item Waiver Request/Approval."**

## 3.8. SELECTION OF HUMAN SUBJECTS AND EVALUATING RISK.

### a. Selection of Human Subjects.

The selection of human subjects in DoD-conducted or DoD-supported HSR must comply with Section 252 of the National Defense Authorization Act for Fiscal Year 1994 (Public Law 103-160), with respect to gender, minority participation, and membership in the Armed Services. The authority to waive the requirements of this statute may be delegated in the CMP.

**(1) (Added)(DAF) DoD-institutions conducting clinical trials supported by DAF will make every effort towards gender- and minority- inclusive recruitment, but are not required to specifically recruit members of the Armed Services per paragraph 3.8.a.**

**(2) (Added)(DAF) AF/SG delegates authority to the DAF COHRP Director to approve waivers per paragraph 3.8.a. This authority cannot be further delegated. Submit waiver requests to the DAF COHRP with a written justification supported by relevant facts and regulatory analysis, with citations. (T-0)**

**(3) (Added)(DAF) Section 3.8.a. only applies to HSR which constitutes a clinical trial as defined by Section 102(b) of Title 32, CFR, "in which one or more human subjects are prospectively assigned to one or more interventions... to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes."**

### b. Evaluating Risk.

The definition of minimal risk in Part 219 of Title 32, CFR, does not 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.

## 3.9. ADDITIONAL PROTECTIONS FOR HUMAN SUBJECTS.

### a. Additional Safeguards.

Provide additional safeguards for subjects who are likely to be vulnerable to coercion or undue influence in accordance with Subparts B, C, and D of Part 46 of Title 45, CFR, and this issuance.

(1) The additional safeguards set forth in Sections 3.9(b)-(f) must be provided in DoD-conducted and DoD-supported HSR.

(2) 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.

**(3) (Added)(DAF) ICDs for DAF-conducted or –supported nonexempt HSR will identify DoD's relationship to the HSR (e.g., as the sponsor) and state the DoD may inspect the research records. This is a DAF interpretation of the requirement of Title 32 CFR Sections 219.116(a)(4) (on information a reasonable person would want to know) and 219.116(b)(5) (on description of limits to confidentiality). The IRB of record for the HSR has authority to waive or alter this requirement per Section 219.116(f) of Title 32, CFR.**

### b. Pregnant Women, Fetuses, and Neonates Involved in Research.

Research involving pregnant women, fetuses, or neonates as human subjects must comply with Subpart B of Part 46, Title 45, CFR, unless modified by this issuance.

(1) For purposes of applying this section, the phrase "biomedical knowledge" in Subpart B of Part 46, Title 45, CFR, is replaced with "generalizable knowledge."

(2) The applicability of Subpart B of Part 46, Title 45, CFR, is limited to research involving pregnant women as human subjects involved in HSR that is greater than minimal risk, and includes interventions, as defined in Part 219 of Title 32, CFR, or invasive procedures involving:

(a) The woman or the fetus; or

(b) Fetuses or neonates as human subjects.

(3) HSR using fetal tissue must comply with Sections 289g–289g-2 of Title 42, U.S.C.

(4) For HSR 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, DoD institutions must demonstrate to the SDO that the IRB has fulfilled its duties in accordance with Subpart B of Part 46, Title 45, CFR. Before HSR activities may begin, the SDO must receive explicit written approval from the DOHRP.

### c. Prisoners as Human Subjects.

HSR involving prisoners as human subjects must comply with Subpart C of Part 46 of Title 45, CFR, unless modified by this issuance.

(1) In addition to the categories of permissible HSR involving prisoners identified in Subpart C of Part 46 of Title 45, CFR, two additional categories are permissible:

(a) Epidemiological research that meets the waiver criteria in accordance with Pages 36929-36931 of Volume 68, Federal Register, may be approved in accordance with the applicable requirements of Subpart C of Part 46 of Title 45, CFR, this issuance, and other applicable requirements.

(b) HSR that would otherwise meet exemption criteria may be conducted, but must first be approved by an IRB and must meet the requirements in Subpart C of Part 46 of Title 45, CFR, this issuance, and other applicable requirements.

(2) DoD institutions conducting research involving prisoners must demonstrate to the SDO that the IRB has fulfilled its duties in accordance with Subpart C of Part 46 of Title 45, CFR.

(3) When a previously enrolled human subject becomes a prisoner, and the protocol has not been reviewed and approved by the IRB in accordance with Subpart C of Part 46 of Title 45, CFR, the key investigator must promptly notify the IRB. For DoD-conducted research, the HPD must notify the COHRP. For DoD-supported research, the non-DoD institution must notify the HRPO and other federal agencies, if required.

### d. Children Involved as Subjects in Research.

HSR involving children as human subjects must comply with Subpart D of Part 46 of Title 45, CFR. DoD institutions must demonstrate to the SDO that the IRB has fulfilled its duties in accordance with Part 407 of Subpart D of Part 46 of Title 45, CFR, and Section 50.54 of Title 21, CFR.

### e. Detainees or Prisoners of War.

Research involving a detainee or a prisoner of war as a human subject is prohibited.

(1) The prohibition in this paragraph does not apply to activities covered by investigational new drug or investigational device provisions of Title 21, CFR, 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 Title 21, CFR, and only when the same product may be available to DoD-affiliated personnel consistent with established medical practices.

### f. DoD-affiliated Personnel as Subjects in DoD-conducted or –supported HSR.

(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.

**(a) (Added)(DAF) The above approval must be documented in writing. The above approval is only required when the HSR is DoD-conducted or -supported. Contact the DAF COHRP for assistance in determining whether proposed officials are authorized to provide command approval or DoD Component approval.**

(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.

**(a) (Added)(DAF) DAF does not accept voluntary services without compensation when such services may provide a basis for a future claim against the government. See Section 1342 of Title 31 U.S.C. Include one of the following statements in each informed consent document for DAF-conducted HSR. (T-1)**

**1. (Added)(DAF) If compensation is not provided, state there are no plans to provide compensation for participation in the research.**

**2. (Added)(DAF) If compensation is provided, state there are no plans to provide other compensation beyond that described in the informed consent document.**

## 3.10. RESEARCH INVOLVING LSGD COLLECTED ON DOD-AFFLIATED PERSONNEL.

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, including the secondary use or sharing of de-identified data or specimens.

**e. (Added)(DAF) DAF personnel will complete the following process before conducting or supporting research involving LSGD collected on DoD-affiliated personnel.**

**(1) (Added)(DAF) Security review of DAF-conducted or –supported research involving LSGD collected on DoD-affiliated personnel will meet the requirements of DoDI 3216.02, related DOHRP guidance, and the following:**

**(a) (Added)(DAF) Categorize the level of risk to national security from disclosure of data to result from the LSGD research (i.e., low, medium, or high). (T-3) Document consideration of the totality of features of the research, e.g., those described in the following subparagraphs. (T-3)**

**1. (Added)(DAF) Consider sample size, e.g.: low-risk (<50 subjects), medium-risk (50-500 subjects), or high-risk (>500 subjects).**

**2. (Added)(DAF) Consider the specificity of the target subject pool, e.g.: low- and medium-risk would involve recruitment of nonspecific DoD-affiliated personnel, and high-risk would involve recruitment of entire units.**

**3. (Added)(DAF) Consider the nature of the target subject pool: low-risk (e.g., personnel from non-deployable units and units operating in fixed facilities); medium-risk (e.g., personnel from conventional operational units which may deploy); or high-risk (special operations forces or personnel from units supporting special operations forces).**

**(b) (Added)(DAF) If information for the LSGD research will be collected, maintained, or disseminated through DoD-owned and DoD-controlled information technology, include consideration of the privacy impact assessment in accordance with AFI 33-332.**

**(c) (Added)(DAF) When such research is deemed sensitive (see Glossary), security personnel performing security reviews will submit to the Air Force Office of Special Investigations a request for technical surveillance countermeasure support (e.g., to identify conditions contributing to technical security vulnerabilities and employ appropriate countermeasures) in**

**accordance with AFI 71-101V3, "The Air Force Technical Surveillance Countermeasures Program."**

**(d) (Added)(DAF) To inform the necessary level of security controls, use: the level of risk determined per paragraph 3.10.e.(1)(a); information from paragraphs 3.10.e.(1)(b) and (c), as applicable; and Table 3, LSGD Research Security Control Examples. (T-3) Document the security controls deemed necessary. (T-3)**

**(Added)(DAF) Table 3. LSGD Research Security Control Examples.**

| | | SECURITY CONTROL EXAMPLES | | |
|---|---|---|---|---|
| | | **Administrative** | **Technical** | **Physical** |
| **RISK** | **Low** | **- Limit public access to some or all data.<br>- Restrict some data to qualified researchers.** | **- Place data in an unrestricted-access repository.<br>- Store data on a key investigator's laptop with encryption software or on a university server with password protection.** | **Store data or specimens in a laboratory or office with general facility-level restrictions on physical access.** |
| | **Medium** | **Use controls above, as appropriate, plus:<br>- Further limit data access to qualified researchers only.<br>- Place data in a restricted-access repository.<br>- Restrict access to a specific dataset for a specific research project only.<br>- Use a data sharing agreement specifying the data will be secured, used only for research purposes, not transferred to others, and no attempt will be made to re-identify individual subjects.** | **Limit access to data:<br>- Store it on a secure server with password protection.<br>- Limit access through a secure login.<br>- Restrict access based on roles and permissions.<br>- Distribute select data directly to a requesting qualified investigator through an electronic file.** | **Use controls above, plus restrictions on access (e.g., only allow unsupervised access to research staff directly involved in the activity).** |

| | | | | |
|---|---|---|---|---|
| | **High** | **Use medium-risk controls above, plus:**<br>**- Document an approval process for requesting investigator access.**<br>**- Redact sensitive or potentially identifiable data.** | **Use medium-risk controls above, plus:**<br>**- Limit access to sensitive data through a data enclave.**<br>**- Store data on a DoD server.** | **Use medium-risk controls above, plus require direct supervision by research staff while data or specimens are being accessed by others for the purpose of sharing.** |

**(e) (Added)(DAF) The person completing the security review will document and sign their review in a memorandum including their determinations on the level of risk to national security and necessary security controls. (T-3)**

**(2) (Added)(DAF) After completion of the security review, the submitting institution will compile the security review package and provides it to the DAF COHRP Director with a request for approval. (T-0) The package will include the following:**

**(a) (Added)(DAF) The completed security review with any documentation supporting the review (e.g., the privacy impact assessment, if applicable).**

**(b) (Added)(DAF) Either documentation of completion of component-level administrative review or documentation required for DAF COHRP completion of such review in accordance with paragraph 3.5.b (for DoD-conducted research) and/or 3.6.a (for DoD-supported research), as applicable.**

**(c) (Added)(DAF) The CoC obtained for the research.**

**(3) (Added)(DAF) The DAF COHRP Director: will assess each security review for compliance with the requirements of this issuance and approve compliant reviews. (T-3)**

**(b) (Added)(DAF) Will provide to the submitting institution written documentation identifying action necessary to address any unresolved compliance issues. (T-3) May disapprove a security review if the submitting institution does not promptly address such unresolved compliance issues.**

**(4) (Added)(DAF) After the DAF COHRP Director approves the security review:**

**(a) (Added)(DAF) Low- and Medium-Risk LSGD Research: The DAF COHRP Director is the final DoD approval authority of the security review for LSGD research of low or medium risk to national security. The DAF COHRP Director submits each approved security review to the DOHRP for informational purposes with CLAR approval of the research, the approved protocol, and any informed consent document(s). (T-0)**

**(b) (Added)(DAF) High-Risk LSGD Research:**

**1. (Added)(DAF) The DAF COHRP Director will submit to the SDO (AF/SG) for approval the security review for LSGD research of high risk to national security. (T-0) The**

**purpose of the SDO's approval of the security review is to confirm appropriate security controls are in place to protect human subjects in light of the high risk to national security. The DAF COHRP Director will provide to the submitting institution written documentation identifying any action the SDO deems necessary to secure approval. (T-3) The SDO will provide a written justification for any disapproval.**

**2. (Added)(DAF) After SDO approval, the DAF COHRP Director submits the security review for high-risk LSGD research to the DOHRP for approval with: the component-level administrative review and approval of the research; the approved protocol; any approved informed consent document(s); and the CoC. (T-0)**

## 3.11. UNIQUE DOD LIMITATIONS ON WAIVER OF INFORMED CONSENT.

a. Sections 219.116(e) and (f) of Title 32, CFR, identify conditions where an IRB may waive informed consent for DoD-conducted and DoD-supported HSR.

b. Section 980 of Title 10, U.S.C.:

(1) Imposes limitations on waiving informed consent when DoD appropriated funds are used to finance the research.

(2) Is applicable only to DoD-conducted and DoD-supported research when involving a human being as an experimental subject as defined in this issuance. Research involving a human being as an experimental subject, governed by Section 980 of Title 10, U.S.C., is a subset of research involving human subjects, regulated by Title 32, CFR.

(3) Is not applicable to exempt HSR.

c. For research involving a human being as an experimental subject to which Section 980 of Title 10, U.S.C., applies, informed consent must be obtained in advance from the experimental subject or the subject's legal representative (consistent with Part 219 of Title 32, CFR, if the subject cannot consent). If consent is obtained from the subject's legal representative, the intention of the key investigator must be for the research to be beneficial to the subject.

d. For research governed by Section 980 of Title 10, U.S.C., that involves no more than minimal risk, as defined by Part 219 of Title 32, CFR, an IRB may alter or waive other required elements of informed consent pursuant to Part 219 of Title 32, CFR, 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 voluntary and includes the requirement that the subject is informed of research risks).

e. The advance informed consent requirement pursuant to Section 980 of Title 10, U.S.C., may be waived by the DOHRP or its delegate, if the following conditions are met:

(1) The research is to advance the development of a medical product necessary to the DoD.

(2) The research may directly benefit the individual experimental subject.

(3) The research is conducted in compliance with all other applicable laws and regulations.

## 3.12. PROTECTING HUMAN SUBJECTS FROM MEDICAL EXPENSES IF INJURED

### a. DoD-Supported Research Involving Human Subjects.

All non-exempt HSR must meet the requirement in Section 219.116 of Title 32, CFR.

### b. DoD-Conducted Research Involving Human Subjects.

All HSR that is determined to be greater than minimal risk must meet the requirement of Section 219.116 of Title 32, CFR, to provide subjects with an explanation as to whether any compensation and any medical treatments are available for research–related injuries.

(1) 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 Part 108 of Title 32, CFR. This eligibility for health care services extends beyond subjects' participation in the study to such time after the study has ended, in accordance with Section 219.108 of Title 32, CFR.

(2) CMPs and institutional HRPPs must document how institutions will care for subjects 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.

**(a) (Added)(DAF) Human subjects who are DoD healthcare beneficiaries (such as active duty military personnel or their dependents) are entitled to the same care for research-related injuries within the Military Health System as they would have for any injury or illness in accordance with Section 1074 of Title 10, U.S.C.**

**(b) (Added)(DAF) Human subjects who are not DoD healthcare beneficiaries and who experience research-related injuries that are a direct result of participation in DAF-conducted HSR of greater than minimal risk may be eligible for treatment of the research-related injury in DoD military treatment facilities as Secretary of Defense designees to the extent permitted in DoDI 6025.23 and DoDI 3216.02 (see also 32 CFR 108.4(i)). Military treatment facility care is limited to the pendency of the volunteer's involvement in the research; extensions require approval in accordance with DoDI 6025.23.**

**(c) (Added)(DAF) Human subjects who are not DoD healthcare beneficiaries and who receive treatment for research-related injuries outside of a DoD military treatment facility (e.g., a local emergency department) will be responsible for the expenses of such treatment (to the extent they are not covered by the subjects' insurance).**

(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.

### c. (Added)(DAF) DAF-Conducted or -Supported Research Involving Human Subjects.

**(1) (Added)(DAF) In addition to the requirement in Section 219.116 of Title 32, CFR, DAF institutions supporting or conducting non-exempt HSR of greater than minimal risk will ensure any related informed consent document includes the following elements.**

**(a) (Added)(DAF) Information about whether any medical treatment available for research-related injuries will be provided free or billed, in whole or in part, to the subject or the subject's insurance company. (T-3)**

**(b) (Added)(DAF) A statement that subjects are not waiving legal rights by signing the informed consent document. (T-3)**

**(c) (Added)(DAF) A statement that DAF does not provide compensation for research-related injuries.**

## 3.13. CLASSIFIED HSR.

a. 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:

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

(2) 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.

(3) Classified information is provided to, or by, research subjects.

b. DoD-conducted or –supported HSR is not considered classified HSR:

(1) 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.

(2) 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 Sections 3.13.b.(1) or (3) also exist.

(3) If the research constitutes an authorized operational activity, then it is not HSR.

c. The DOHRP is the final approval authority for all DoD-conducted or DoD-supported classified HSR. The SDO prospectively conducting or supporting the HSR must submit a package to the DOHRP for approval to conduct the classified HSR.

**(1) (Added)(DAF) Submit all proposed DAF-conducted or -supported classified HSR to the appropriate CLAR official for review (see paragraph 2.8.i) prior to submission to the DOHRP.**

**(T-0) After CLAR approval, the DAF COHRP prepares the package for the DOHRP in accordance with paragraph 3.1.k.**

d. No DoD agency within the Intelligence Community may sponsor, contract for, or conduct non-exempt HSR except in accordance with Paragraph 2.10 of Executive Order 12333 and DoD 5240.1.

## 3.14. ADDITIONAL PROTECTIONS FOR PRIVACY AND CONFIDENTIALITY IN RESEARCH.

There are certain authorities that the DoD Components may consider using for sensitive research.

### a. Confidential Information Protection and Statistical Efficiency Act for Non-Statistical Agencies.

Any DoD Component may use the authority pursuant to Sections 501-513 of the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) (Public Law 107-347) to assure that 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. Use of this authority is subject to the requirements of CIPSEA Sections 512 and 523-525 and of Volume 72, Federal Register.

**(1) (Added)(DAF) All proposals to use authority under CIPSEA must have CLAR prior to implementation. (T-1)**

### b. CoC.

A DoD institution conducting HSR or non-DoD institution conducting HSR with DoD support may request a CoC pursuant to Section 241 of Title 42, U.S.C. All studies involving LSGD collected on DoD-affiliated personnel will apply an HHS CoC.

(1) A CoC prohibits disclosing or providing, in any federal, State, or local civil, criminal, administrative, legislative, or other proceeding, or to any other person not connected with the research, the name of any individual or any such information, document, or biospecimen that contains identifiable information about the individual, created or compiled for purposes of research.

(2) Exceptions to the CoC must be listed in all informed consent documents, pursuant to this issuance and as stated in Section 241 of Title 42, U.S.C.

**(a) (Added)(DAF) The CoC does not protect against disclosure in all circumstances. To the extent that disclosure is required by Federal, state, or local laws, disclosure in the following circumstances may be permissible:**

**1. (Added)(DAF) The individual poses a serious threat to self or others.**

**2. (Added)(DAF) Child abuse or neglect is known or suspected.**

**3. (Added)(DAF) Certain communicable or infectious diseases require reporting to the Centers for Disease Control and Prevention or other public health entities.**

**(3) (Added)(DAF) If any information regarding the HSR (e.g., participation or findings) will be included in subjects' medical records, the HSR review authority will take appropriate action to maximize protection of subjects (e.g., require omission of this information from the medical records, if appropriate, or disclose in the ICD this limit to the CoC's protection).**

## 3.15. RECORD-KEEPING.

a. Part 219 of Title 32, CFR, requires all institutions engaged in DoD-conducted or DoD-supported HSR to retain records for at least 3 years after the completion of the research, or longer if required by DoD Manual 6025.18, the Privacy Act, FDA regulations, or other applicable requirements.

b. For complete record-keeping guidance and instruction, DoD institutions must consult their records disposition schedules.

c. Records maintained by non-DoD institutions that document compliance or noncompliance with this issuance must be accessible for inspection and copying by authorized representatives of the DoD

## 3.16. NONCOMPLIANCE.

a. DoD institutions must promptly respond to allegations of noncompliance with this issuance.

**(1) (Added)(DAF) DAF institutions will follow noncompliance procedures included in their HRPP plans in accordance with paragraph 3.3.h.(17).**

**(2) (Added)(DAF) DAF institutions in receipt of allegations of noncompliance with this issuance from private citizens will request information necessary to allow investigation of the allegation, including: protocol title, name of investigator, research location, and dates of related research events. Allegations which are not supported by such information will be referred for action to the Air Force Office of Special Investigations.**

b. For allegations involving a non-DoD institution, the non-DoD institution must conduct an investigation in accordance with the applicable support agreement, to be furnished to the supporting DoD organization via the HRPO. The DoD institution supporting the HSR must ensure in its agreements with the non-DoD institution that allegations are promptly and properly investigated. The DoD institution will then promptly report substantiated serious and/or continuing non-compliance findings to the COHRP.

**(1) (Added)(DAF) For the purposes of the paragraph above, "applicable support agreement" is the agreement through which the DoD support is provided (e.g., contracts, grants, and other assistance agreements). See paragraph 3.6.b.(1).**

**(2) (Added)(DAF) When furnishing reports of substantiated serious and/or continuing non-compliance findings to the HRPO, include a copy of the applicable support agreement. (T-3)**

c. Substantiated allegations related to classified HSR must be reported immediately to the DOHRP.

**(1) (Added)(DAF) Submit such substantiated noncompliance to DAF COHRP, which will report to the DOHRP. (T-0)**

**d. (Added)(DAF) Upon identification of noncompliance by the DAF COHRP (e.g., in conjunction with compliance assessments), the DAF COHRP Director investigates, determines whether it is serious or continuing, and, if so, reports this to the IO and the DOHRP. (T-0) The DAF COHRP Director collaborates with personnel of the DAF institution conducting or supporting the noncompliant activity (e.g., their HPD or IRB chair) to create appropriate corrective action plans to resolve the noncompliance in a timely manner.**

## 3.17. CCHRPP MEMBERSHIP.

The CCHRPP is composed of senior officials at the general officer/flag officer, Senior Executive Service, or equivalent level.

a. Each SDO must identify one regular and one alternate member to represent their component to the CCHRPP, and must promptly notify the DOHRP if those designations change.

b. The CCHRPP Chair is the Director, Human Systems Directorate, Office of the USD(R&E).

c. The Executive Secretariat to the CCHRPP is composed of the COHRP directors, or equivalent authorities from the DoD Component HRPP oversight bodies, and those deemed necessary to the Executive Secretariat's missions by the DOHRP Director.

(1) The Executive Secretariat is referred to as the DC; its Chair is the Director, DOHRP.

(2) The DC acts as a central advisory committee to the DoD, the USD(R&E), and the DOHRP on matters regarding HSR, privacy issues in research, ethical, legal, and social implications in research.

(3) The DC may act as an ethics panel or body and designate subcommittees as needed.

## 3.18. (ADDED)(DAF) CONTINUITY OF OPERATIONS.

**(Added)(DAF) This section describes the DAF HRPP Continuity of Operations Strategy (hereinafter referenced as "Strategy"). It applies in any government closure situation resulting in forced reduction in HRPP personnel, regardless of duration, scope (e.g., local, partial (e.g., furlough), or national) or cause (e.g., as a result of weather, appropriation lapse, etc.). Its purpose is to maintain HRPP operations to ensure the safety, rights, and welfare of participants in HSR.**

**a. (Added)(DAF) For closures anticipated to be short (less than thirty consecutive calendar days), the following requirements apply.**

**(1) (Added)(DAF) The DAF COHRP Director is deemed essential to ensure continuing protection of human subjects in DAF-conducted or -supported HSR. (T-1)**

**(2) (Added)(DAF) Each DAF institutional HRPP will include a continuity of operations plan for continuing HSR to avoid harm to subjects, including the following elements. (T-1):**

**(a) (Added)(DAF) If possible, at least one mission essential government employee sufficient to carry on minimal duties necessary to protect human subjects (e.g., IRB functions, HRPO functions, and reporting (e.g., of unanticipated problems involving risks to human subjects or others, as well as serious or continuing non-compliance)). If not possible to maintain staffing, HRPP offices may refer customers to an alternative HRPP office.**

**(b) (Added)(DAF) IOs will assess whether any ongoing HSR can continue or must stop. (T-3) Provide to non-DoD institutions conducting DAF-supported HSR and subjects in DAF conducted HSR appropriate alternate HRPP contacts. (T-3) If the key investigator or research monitor (when required by the IRB) is furloughed without an alternate, the HSR must stop until resumption of the duty if stopping the HSR does not pose a risk of harm to the human subjects. (T-1) If protocol deviations are necessary to ensure subject welfare, the key investigator will get prior IRB approval, if possible; if not possible, report these to the IRB as soon as possible. (T-3)**

**b. (Added)(DAF) For closures anticipated to be long term (i.e., lasting more than 30 consecutive calendar days), the provisions above will also be executed, where possible. Each affected IO (or their AIO) will report to the DAF COHRP their plan of action and HRPP status. (T-1) The DAF COHRP will assess the plan and respond accordingly (e.g., via acknowledgment with no action necessary, request for additional corrective action, or suspension of the institution's HRPP). The DAF COHRP will report to the SDO whether the DAF maintains sufficient resources to continue research activities and recommend appropriate courses of action, as needed.**

## 3.19. (ADDED)(DAF) ARTIFICIAL INTELLIGENCE (AI).

**(Added)(DAF) All DAF-conducted or –supported HSR (exempt or nonexempt) involving AI-enabled tools or capabilities will:**

**a. (Added)(DAF) Comply with the DoD ethical principles for AI included in the Deputy Secretary of Defense Memorandum, "Implementing Responsible Artificial Intelligence in the Department of Defense." (T-0) Describe provisions to meet each of the DoD ethical principles for AI. (T-3)**

**b. (Added)(DAF) Include in any required scientific merit review, and document in writing, consideration of whether the DoD ethical principles for AI are appropriately implemented. (T-3)**

# GLOSSARY

## G.1. ACRONYMS.

| ACRONYM | MEANING |
|---|---|
| **(Added)(DAF) AF** | **Air Force** |
| **(Added)(DAF) AFI** | **Air Force instruction** |
| **(Added)(DAF) AFMED** | **Air Force Medical** |
| AIO | alternate institutional official |
| **(Added)(DAF) CC** | **Commander** |
| CCHRPP | Coordinating Committee for HRPPs |
| CFR | Code of Federal Regulations |
| CIPSEA | Confidential Information Protection and Statistical Efficiency Act of 2002 |
| CLAR | component-level administrative review |
| CMP | component human research protection program management plan |
| CoC | certificate of confidentiality |
| COHRP | component office of human research protections |
| **(Added)(DAF) DAF** | **Department of the Air Force** |
| **(Added)(DAF) AF/SG** | **Department of the Air Force Surgeon General** |
| DC | DoD Office for Human Research Protections Cabinet |
| DFARS | Defense Federal Acquisition Regulation Supplement |
| **(Added)(DAF) DoD** | **Department of Defense** |
| DoDI | DoD instruction |
| DOHRP | DoD Office for Human Research Protections |
| EDO | exemption determination official |
| FAR | Federal Acquisition Regulation |
| FDA | Food and Drug Administration |
| FWA | federal-wide assurance |
| HHS | Department of Health and Human Services |
| **(Added)(DAF) HIPAA** | **Health Insurance Portability and Accountability Act** |
| HPD | human protections director |
| HRPO | human research protection official |
| HRPP | human research protection program |
| HSR | human subject research |
| ICD | informed consent document |
| IIA | individual investigator agreement |
| IAIR | institutional agreement for IRB review |
| IO | institutional official |

| ACRONYM | MEANING |
|---|---|
| IRB | institutional review board |
| LSGD | large-scale genomic data |
| SDO | senior designated official |
| **(Added)(DAF) U.S.** | **United States** |
| U.S.C. | United States Code |
| USD(R&E) | Under Secretary of Defense for Research and Engineering |

## G.2. DEFINITIONS.

Unless otherwise noted, these terms and their definitions are for the purpose of this issuance.

| TERM | DEFINITION |
|---|---|
| administrative review | Review of research to ensure compliance with regulations and policies applicable to HSR that is DoD conducted or research where DoD provides support. |
| **(Added)(DAF) AIO** | **A person to whom the IO has delegated authority and responsibility to fulfill the IO's duties for the purposes of overseeing the institution's HRPP.** |
| **(Added)(DAF) artificial intelligence** | **The ability of machines to perform tasks that normally require human intelligence (e.g., recognizing patterns, learning from experience, drawing conclusions, making predictions, or taking action) whether digitally or as the smart software behind autonomous physical systems. See Summary of the 2018 DoD AI Strategy.** |
| assistance | Non-financial resources that are provided by the DoD to non-DoD institutions for research, including, but not limited to, facilities, equipment, access to information about DoD-affiliated personnel for recruitment, access to DoD-affiliated personnel, data, or specimens. Funds that are provided by the DoD through a contract or similar arrangement subject to the DFARS; grants, cooperative agreements, technology investment agreements; or other non-procurement awards are not considered assistance. Assistance is a subset of support. |
| authorized operational activities | Activities carried out solely in support of the DoD mission to provide military forces information needed to deter war and to protect the security of the United States. These activities are subject to approval by the DoD Component head or Secretary of |

| TERM | DEFINITION |
| --- | --- |
| | Defense, including subordinate agencies heads who have been delegated authority to study, evaluate, improve, or otherwise assess DoD performance, quality, and capability.<br><br>**(Added)(DAF) It is the DAF position that HSR is designed to develop or contribute to generalizable knowledge and, thus, is not carried out "solely" in support of the DoD mission.** |
| certification | Official notification by an institution that HSR has been reviewed and approved by an IRB. |
| classified research involving human subjects | Research involving human subjects where classified material is necessary to adequately perform IRB review and oversight, required to obtain effective informed consent of participants, or, by design, communicated by or to research participants. |
| **(Added)(DAF) Common Rule** | **The regulation adopted by multiple Federal departments and agencies for the protection of human subjects in research. The DoD's implementation of the Common Rule is 32 Code of Federal Regulations (CFR) part 219; the Department of Health and Human Services' implementation of the Common Rule is subpart A of 45 CFR part 46.** |
| **(Added)(DAF) continuing noncompliance** | **A pattern of noncompliance (see definition of noncompliance) that suggests the likelihood that, without intervention, instances of noncompliance will recur. A repeated unwillingness to comply with this issuance or a persistent lack of knowledge of how to comply with this issuance.** |
| detainee | Defined in DoD Directive 2310.01E. |
| DoD-affiliated personnel | Service members, Reserve Service members, National Guard members, DoD civilians, and DoD contractors. |
| DoD assurance | A written document stating an institution will comply with 32 CFR Part 219 (the Common Rule), and DoD and DoD Component policies. |
| **(Added)(DAF) DoD-conducted HSR** | **Research involving human subjects that is either performed by DoD personnel or is performed by DoD contract personnel with direct oversight by a key investigator who is federal employee of a DoD institution. See "engaged in HSR." HSR can be both DoD-conducted and non-DoD conducted (e.g., through collaborations between DoD and non-DoD institutions).** |

| TERM | DEFINITION |
| --- | --- |
| DoD institution | A DoD entity which conducts activities that may be HSR.<br><br>**(Added)(DAF) Includes DoD entities which support or provide research reviews (see Table 1) of activities that may be HSR.** |
| **(Added)(DAF) engaged in HSR** | **An institution is engaged in HSR when its personnel conduct the HSR on behalf of the institution. An institution is not engaged in HSR if their activities are limited to: funding; providing equipment; providing access to or information about potential human subjects (but not recruiting human subjects); providing data or specimens (either identifiable or not); or overseeing the research from a compliance standpoint.** |
| excluded activities | The following activities conducted or supported by the DoD are not considered HSR:<br><br>Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease under force health protection programs of DoD, including health surveillance pursuant to Section 1074f of Title 10, U.S.C., and the use of medical products consistent with DoDI 6200.02.<br><br>Health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of diagnosis, cure, mitigation, treatment, or prevention of disease in a patient.<br><br>Activities performed for the sole purpose of medical quality assurance (see Section 1102 of Title 10, U.S.C., and DoDI 6025.13).<br><br>Activities that meet the definition of operational test and evaluation as defined in Section 139(a)(2)(A) of Title 10, U.S.C.<br><br>Activities performed solely for assessing compliance, including occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information.<br><br>Activities, including program evaluation and surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results are only for the |

| TERM | DEFINITION |
|---|---|
| | use of government officials responsible for the operation or oversight of the program being evaluated. |
| exempt HSR | HSR that meets specific federal criteria in 32 CFR Part 219, falling into one of the eight categories of Exempt research listed at 32 CFR 219.104. Exempt HSR must be initially determined as Exempt by an IRB, its designee, or designated DoD HRPP personnel, and then is exempt from further review. See also non-exempt HSR. |
| exemption determination official | A federal employee at a DoD institution who, sufficiently qualified through experience and expertise, is designated to review research to determine whether the research involves human subjects and, if so, whether such research is exempt from Part 219 of Title 32, CFR. |
| federal assurance | A written document in which an institution, not an IRB, commits to a federal department or agency its compliance with the requirements set forth in the Common Rule. |
| FWA | A Federal-Wide Assurance which is only issued by the Department of Health and Human Services (HHS). This is required when research is funded by HHS. |
| HPD | The federal employee at a DoD institution who is sufficiently qualified through experience and expertise and serves as the primary point of contact for the DoD institution's HRPP, and who plays a key role in ensuring that the institution fulfills its responsibilities under the institution's federal assurance or HRPP. |
| HRPO | A federal employee designated by a DoD Component or institution to conduct administrative review of DoD-supported research in accordance with the requirements of the DFARS, or comparable requirement, and whose review of DoD-supported research is intended to ensure compliance with DoD HSR requirements. |
| HRPP | An institution's system of interdependent elements that implement policies and practices to protect human subjects involved in research. An institution with an HRPP may or may not hold a DoD or federal assurance. |
| **(Added)(DAF) HRPP plan** | **The written description of the HRPP. For requirements applicable to DAF institution-level HRPP plans, see paragraphs 3.3.a and 3.3.h.** |

| TERM | DEFINITION |
|---|---|
| HSR | Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge and involve a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, or identifiable private information, or biospecimens. |
| human subject | A living individual about whom an investigator (whether professional or student) conducting research:<br><br>Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or<br><br>Obtains, uses, studies, analyzes, or generates identifiable private information, personally identifiable information, or identifiable biospecimens. |
| individual investigator agreement | An agreement between an investigator and an assured institution where the investigator acknowledges that they are primarily responsible for upholding the standards as set forth in the institution's assurance; meanwhile, the institution agrees to extend its assurance, or "cover", the individual investigator. |
| institution | Any public or private entity, which conducts activities that may be HSR. |
| **(Added)(DAF) institutional agreement for IRB review (IAIR)** | **An agreement which allows an institution engaged in HSR to rely upon the IRB of another institution. It describes the responsibilities of the institution engaged in HSR and the institution with the IRB. An IAIR can cover one, several, or all protocols in which the institution is engaged.** |
| intervention | Includes both physical procedures by which information or biospecimens are gathered (*e.g.,* venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. |
| IO | An institution's senior person who is legally authorized to represent the institution and who is authorized to establish and is responsible to maintain the HRPP for the institution. The IO is responsible for the institution's DoD or federal assurance and IRB, if these elements are part of the institution's HRPP. |

| TERM | DEFINITION |
| --- | --- |
| | **(Added)(DAF) The term "IO" is only used for an institution with a DoD or federal assurance. In this publication, references to the "IO" mean either the IO of an assured institution or, if it does not have an assurance, the institution's commander or director, as applicable. Further, for assured institutions, references to the IO can be applied to the AIO (if any) to the extent not otherwise prohibited herein.** |
| key investigator | The person leading the performance of research.<br><br>**(Added)(DAF) Also known as the principal investigator.** |
| LSGD | Data derived from genome-wide association studies; single nucleotide polymorphisms arrays; genome sequencing; transcriptomic, metagenomic, epigenomic analyses; and gene expression data; etc. Research involving LSGD may or may not also constitute HSR. Examples of research involving LSGD includes, but is not limited to, projects that involve generating the whole genome sequence data for more than one gene from more than 1,000 individuals, or analyzing 100 or more genetic variants in more than 1,000 individuals. |
| non-exempt HSR | HSR that meets specific federal criteria in 32 CFR Part 219 and this issuance for minimal risk or greater than minimal risk.<br><br>**(Added)(DAF) In addition to the above, non-exempt HSR meets the definitions of "research" involving "human subjects" but does not meet the criteria where the only involvement of the human subjects in the research are in one or more of the categories identified in Section 219.104(b) of Title 32, CFR.** |
| Ombudsperson | A person who acts as an impartial and objective advocate for human subjects participating in research. |
| post-approval compliance monitoring | Formal and systematic HRPP monitoring of research to confirm that HSR is being conducted in accordance with IRB approval or other HRPP regulatory determinations, institutional HRPP policy and procedures, applicable federal laws and regulations, and DoD policy. |
| protocol | A document that describes the background, rationale, objectives, design, methodology, and organization of a research investigation. In HSR, the protocol is frequently synonymous with the application for approval of a research study to an IRB. |

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| research | A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this issuance, whether or not they are conducted or supported under a program that is considered research for other purposes. The following activities are deemed not to be research:<br><br>Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.<br><br>Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).<br><br>Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.<br><br>Authorized operational activities (as determined by each DoD Component) in support of intelligence, homeland security, defense, or other national security missions. Guidance and approval for determining authorized operational activities with regard to HSR will be issued by the DOHRP. |
| research involving a human being as an experimental subject | 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 a human being as an experimental subject is a subset of research involving human subjects. This |

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| | definition relates only to the application of Section 980 of Title 10, U.S.C.; it does not affect the application of Part 219 of Title 32, CFR. |
| **(Added)(DAF) HSR review authority** | **HRPP personnel responsible for reviewing activities that include (or are likely to include) HSR to ensure compliance with this issuance, its references, and the institution's HRPP plan. Includes EDOs, IRBs, HRPOs, and personnel with CLAR authority. For a description of each HSR review authority type, see Table 1.** |
| security review | Administrative review of research involving large-scale genomic data collected on DoD-affiliated personnel to ensure compliance, in accordance with the CMP, as well as administrative, technical, and physical safeguards for protecting confidentiality. |
| **(Added)(DAF) sensitive** | **An agency, installation, person, position, document, material, or activity requiring special protection from disclosure that could cause embarrassment, compromise, or threat to the security of the sponsoring power.** |
| **(Added)(DAF) serious noncompliance** | **Failure of a person, group, or institution to act in accordance with this issuance and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.** |
| Service members | Individuals appointed, enlisted, or inducted for military service under the authority of the DoD. The Military Services are the Army; the Navy, including the Coast Guard under circumstances involving the declaration of war; the Air Force; the Marine Corps; and the Reserve Components. Members of the Reserve Components are included when in a duty status. |
| **(Added)(DAF) site visit** | **An in-person or remote visit conducted to evaluate compliance of an institution's HRPP (or a proposed HRPP). See also paragraph 3.2.a.(3)(a).** |
| **(Added)(DAF) staff assistance visit** | **An in-person or remote visit requested by an IO which may help an institution better understand the intent of this issuance and allow an opportunity to provide training.** |

| TERM | DEFINITION |
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| **(Added)(DAF) substantive change** | **An amendment to an approved item which changes it to the extent it requires new review prior to initiation.**<br><br>**Examples of substantive changes to HRPPs include, but are not limited to, establishment of a new IRB or other new HSR review authority function (i.e., not previously performed by the institution); changes in HRPP signatory officials; or changes to the description of the institution.**<br><br>**Examples of substantive changes to non-DoD conducted activities requiring HRPO approval prior to start per paragraph 3.6.b include but are not limited to:**<br>**1. Addition of any condition identified in paragraph 3.6.a.**<br>**2. Addition of institutions to be engaged in non-exempt HSR.**<br>**3. Change in the IRB's review procedure (e.g., from exempt to expedited, expedited to convened board, etc.).**<br>**4. Change in research-related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.**<br>**5. Addition of human subjects who cannot provide informed consent (see Section 980 of Title 10, U.S.C.).**<br>**6. Addition of a research site in a foreign country to include non-U.S. citizens as human subjects.** |
| **(Added)(DAF) suspension of IRB approval** | **IRB action to require HSR to stop for any length of time short of permanent. An action constitutes suspension regardless of the verbiage used by the IRB in taking such action.** |
| support | Funds or assistance that are provided by the DoD to non-DoD institutions for HSR through a grant, contract, or similar arrangement subject to the DFARS or other applicable DoD regulations, such as the DoD Grant and Agreement Regulations.<br><br>Included in this definition is the DoD's provision of assistance to non-DoD institutions, whether or not through collaboration between DoD and non-DoD institutions, such as facilities, equipment, personnel (investigators or other personnel performing tasks identified in the research protocol), access to or information about DoD-affiliated personnel for recruitment, or data or specimens.<br><br>This definition does not include DoD-conducted HSR, whether or not conducted in collaboration between a DoD institution and non-DoD institution. |

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| | **1. (Added)(DAF) HSR is not considered to be DoD-supported when a DoD employee conducts it either with formal authorization to pursue it separate from their DoD position, or otherwise in an off-duty status, if the HSR does not otherwise involve the DoD.**<br><br>**2. (Added)(DAF) Legal transfer (e.g., through sale or donation) of equipment from the DoD to non-DoD institution, when not done by the DoD for the purpose of enabling specific HSR, severs the relationship with the DoD, and the transfer is not considered DoD support.** |
| **(Added)(DAF) unanticipated problem involving risks to human subjects or others** | **Any incident, experience, or outcome that meets all three of the following conditions:**<br><br>**1. Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the HSR protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.**<br><br>**2. Is related (or possibly related) to participation in the HSR. In this issuance, "possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by HSR procedures.**<br><br>**3. Suggests that the HSR places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has occurred.** |

# REFERENCES


**(Added)(DAF) Air Force Mission Directive 35, "Air Force Medical Readiness Agency," May 11, 2022**

**(Added)(DAF) AFI 33-322, "Records Management and Information Governance Program," July 28, 2021**

**(Added)(DAF) AFI 33-332, "Air Force Privacy and Civil Liberties Program," March 10, 2020**

**(Added)(DAF) AFI 41-200, "Health Insurance Portability and Accountability Act (HIPAA)" July 25, 2017**

**(Added)(DAF) AFI 71-101V3, "The Air Force Technical Surveillance Countermeasures Program," May 21, 2019**

**(Added)(DAF) Air Force Manual 36-2664, "Personnel Assessment Program," 18 January 2023**

Belmont Report, 44 Fed Reg 23192

U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health, HHS Publication No. (CDC) 21-1112, "Biosafety in Microbiological and Biomedical Laboratories (BMBL)," current edition

Code of Federal Regulations, Title 21

Code of Federal Regulations, Title 24

Code of Federal Regulations, Title 32

Code of Federal Regulations, Title 45, Part 46, Subparts B, C, D, and E

**(Added)(DAF) DAFI 90-302, "The Inspection System of the Department of the Air Force," March 15, 2023**

**(Added)(DAF) DAFMAN 90-161, "Publishing Processes and Procedures," April 15, 2022**

**(Added)(DAF) Deputy Secretary of Defense Memorandum, "Continuing Implementation of the Reform of the Military Health System," October 25, 2019**

**(Added)(DAF) Deputy Secretary of Defense Memorandum, "Implementing Responsible Artificial Intelligence in the Department of Defense," May 26, 2021**

Defense Federal Acquisition Regulation Supplement, current edition

Deputy Secretary of Defense Memorandum, "Establishment of the Office of the Under Secretary of Defense for Research Engineering and the Office of the Under Secretary of Defense for Acquisition and Sustainment," July 13, 2018

DoD 5240.01-R, "Procedures Governing the Activities of DoD Intelligence Components that Affect United States Persons," December 7, 1982, as amended

DoD Directive 2310.01E, "DoD Detainee Program," March 15, 2022

DoD Directive 5137.02, "Under Secretary of Defense for Research and Engineering (USD(R&E))," July 15, 2020

**(Added)(DAF) DoD 5500.07-R, "Joint Ethics Regulation," August 30, 1993**

DoD Instruction 1100.13, "DoD Surveys," January 15, 2015, as amended

**(Added)(DAF) DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research," April 15, 2020, as amended**

**(Added)(DAF) DoDI5000.89_DAFI99-103, "Capabilities-Based Test and Evaluation," December 9, 2021**

DoD Instruction 6025.13, "Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS)," February 17, 2011, as amended

DoD Instruction 6025.23, "Healthcare Eligibility Under the Secretarial Designee (SECDES) Program and Related Special Authorities," September 16, 2011, as amended

DoD Instruction 6200.02, "Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Program," February 27, 2008

DoD Instruction 8910.01, "Information Collection and Reporting," May 19, 2014, as amended

DoD Manual 6025.18, "Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs," March 13, 2019

DoD Manual 6055.18, "Safety Standards for Microbiological and Biomedical Laboratories," August 11, 2020

DoD Manual 8910.01, Volume 1, "DoD Information Collections Manual: Procedures for DoD Internal Information Collections," June 30, 2014, as amended

DoD Manual 8910.01, Volume 2, "DoD Information Collections Manual: Procedures for DoD Public Information Collections," June 30, 2014, as amended

**(Added)(DAF) DoDI5200.48_DAFI16-1403, "Controlled Unclassified Information (CUI)," October 5, 2021**

**(Added)(DAF) DoDM5200.01V1_AFMAN16-1404V1, "Information Security Program: Overview, Classification, and Declassification," April 6, 2022**

Executive Order 12333, "United States Intelligence Activities," as amended, December 4, 1981, as amended

Executive Order 13526, "Classified National Security Information," December 29, 2009

Federal Register, Volume 44, Page 23192, April 18, 1979

Federal Register, Volume 68, Pages 36929-36931, June 20, 2003

Federal Register, Volume 72, Pages 33361-33377, June 15, 2007

Federal Register, Volume 81, Page 78380

**(Added)(DAF) Headquarters of the Air Force (HAF) Mission Directive 1-48, "The Air Force Surgeon General," February 21, 2023**

National Institutes of Health, "The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)," April 2016

**(Added)(DAF) Note: The current edition of the above NIH reference is dated December 2022**

**(Added)(DAF) Office of the Assistant Secretary of Defense for Research and Engineering Memorandum, "Minimum Education Requirements for DAF Personnel Involved in Human Research Protection," August 16, 2012**

Public Law 103-160, Section 252, "National Defense Authorization Act for Fiscal Year 1994," November 30, 1993

Public Law 107-347, "Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)," December 17, 2002

Public Law 114-255, "21st Century Cures Act," December 13, 2016

**(Added)(DAF) Uniform Code of Military Justice**

United States Code, Title 10

United States Code, Title 24, Section 30

**(Added)(DAF) United States Code, Title 31, Section 1342**

United States Code, Title 42

United States Code, Title 5

United States Code, Title 50, Section 1520a

**(ADDED)(DAF) FORMS**

**DAF Form 679, "Department of the Air Force Publication Compliance Item Waiver Request/Approval"**
**DAF Form 847, "Recommendation for Change of Publication"**
**Office of Government Ethics Form 450, "Confidential Financial Disclosure Report"**

# (ADDED)(DAF) ATTACHMENT 1: LIMITED HRPP

**Instructions:**

**1. This Limited Human Research Protection Program ("Limited HRPP") will only be executed by DAF commands without existing, full HRPPs whose personnel seek to either:**

**a. Conduct exempt human research or**

**b. Support human research.**

**See Reference (a) below for definitions. See References for HRPP requirements.**

**2. Print on command letterhead with the Commander's signature. Alternatively, the Commander can send the below text from their e-mail account. Delete these instructions before issuance.**

**3. This Limited HRPP references "commands." If the entity executing this Limited HRPP is not a command, insert the appropriate substitute term(s).**

**4. The DAF COHRP has only pre-approved use of this Limited HRPP for coverage of a single human research activity (to be identified in paragraph 2 below). If substantive changes to this Limited HRPP are necessary beyond those permitted by the instructions (e.g., to increase scope beyond a single activity):**

**a. Remove the statement that this is pre-approved by the DAF COHRP (see paragraph 2 below) and**

**b. Submit the signed letter to the DAF COHRP for approval prior to initiation of the research.**

**5. Submit the signed Limited HRPP to the DAF COHRP at usaf.pentagon.af-sg.mbx.afmsa-sge-c@health.mil prior to initiation of the research. Contact the DAF COHRP with questions.**

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**LETTERHEAD**

**References: (a) DoDI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research***

**(b) DoDI3216.02_DAFI40-402, *Protection of Human Subjects and Adherence to Ethical Standards in Department of the Air Force (DAF)-Conducted and -Supported Research***

**Subject: DAF Command Approval of Human Research and Establishment of a Limited Human Research Protection Program (HRPP) Plan**

**1. As the commander of [INSERT NAME OF DAF COMMAND], I have reviewed and approved my command's involvement in the following human research study:**

**Study Title: [INSERT]**
**Principal Investigator: [Rank, Name, Office Symbol]**
**Protocol Date: [INSERT]**

**Involvement of this Command: [EDIT AS NEEDED: Conduct exempt human research and/or support human research, such as by providing funds, personnel, identifiable data, facilities, and/or equipment]**
**Name of DoD Research Review Authority (i.e., exemption determination official (EDO), institutional review board (IRB), or human research protection official (HRPO): [ADD NAME AND CONTACT INFORMATION. IF NONE, STOP AND CONTACT THE DAF COHRP. IF THE NAMED EDO, IRB, OR HRPO IS OUTSIDE THE COMMAND OF THE SIGNATORY OFFICIAL OF THIS LIMITED HRPP, THE EDO, IRB CHAIR, OR HRPO MUST ENDORSE THIS MEMO FOR IT TO BE EFFECTIVE.]**

**2. I hereby establish a Limited Human Research Protection Program (HRPP) for the above-referenced study in accordance with the References. This Limited HRPP is limited to the study identified above. The terms of this Limited HRPP have been pre-approved by the (DAF) Component Office of Human Research Protections (COHRP) (AFMED Agency/SGE-C) and are effective upon my signature. See also Reference (b), Attachment 1.**

**a. I am the official responsible on behalf of this command for this HRPP and compliance with the References.**

**b. This command will rely upon the DAF Research Review Authority identified above for the purposes of the study identified above.**

**i. We will contact the DAF Research Review Authority identified above if there are any problems with above-referenced research, such as unanticipated problems involving risk to human subjects or alleged noncompliance.**

**ii. [IF APPLICABLE, ADD ADDITIONAL REQUIREMENTS OF THE REVIEWING DAF IRB OR EDO, E.G., "We will comply with the following additional requirements of the DAF Research Review Authority:"]**

**c. I will enforce the requirements of the References, which state that military and civilian supervisors, officers, and others in the chain of command:**

**i. Are prohibited from influencing their subordinates to participate in any human research.**

**ii. Must not be present at any human research recruitment sessions or during the informed consent process.**

**d. [REMOVE THIS LINE IF A RESEARCHER ON THE STUDY IS NOT A MEMBER OF THE SIGNATORY'S COMMAND] My personnel conducting this exempt human research will obtain publication clearance review from my command before publishing or otherwise releasing findings from this research to members of the public (e.g., via abstracts).**

**e. Before any other new human research proposed to be conducted or supported by this command begins, I will ensure the following occurs:**

**i. I will ensure a DoD Research Review Authority issues a determination allowing the new human research to begin in accordance with the References. If the researcher requesting this command's conduct of or support to human research does not have a DoD Research Review Authority, I will ensure my personnel contact the DAF COHRP to obtain contact information for a DAF Research Review Authority to provide the required determination.**

**ii. I will establish an appropriate HRPP to cover the human research as required by the References. The DAF COHRP authorizes use of the Limited HRPP for up to four (4) activities each year per institution. I will contact the DAF COHRP to establish a full, more detailed HRPP if my institution will conduct or support five (5) or more human research activities in a one-year period.**

**iii. I (or my designee) will approve the research on behalf of this command.**

**f. I will ensure this approval is sent to the DAF COHRP after I sign it to ensure their awareness and oversight in accordance with this Limited HRPP.**

**3. The DAF COHRP has oversight of this Limited HRPP and the above-referenced research in accordance with the References.**

**a. The DAF COHRP will include the above research in their index of human research for the following purposes:**

**i. Annual report to the DoD Office for Human Research Protections within the Under Secretary of Defense for Research and Engineering per Reference (a) and**

**ii. Consideration of post-approval compliance monitoring in accordance with the References.**

**b. I have instructed my point of contact for HRPP purposes (i.e., the "human protections director" required by Reference (a); see paragraph 5 below) to contact the DAF COHRP with any questions about the above-referenced research or any other activity that is potential human research involving this command. My POC will rely upon the DAF COHRP or their designee to provide additional human research protections direction, as needed. For example, the DAF COHRP will evaluate and improve this Limited HRPP and contact me if any updates are deemed necessary to ensure protection of human subjects.**

**4. By endorsing this request, I affirm I have considered the local research context and mission impacts of this research. I have determined this research is worth the time and cost of DAF support.**

**5. My federal employee point of contact for HRPP purposes is [NAME]. They are responsible for implementing my command's responsibilities identified herein in satisfaction of the "human protections director" role required by Reference (a). They can be reached at [e-mail] or [phone]. The DAF COHRP can be reached at usaf.pentagon.af-sg.mbx.afmsa-sge-c@health.mil.**

**COMMANDER SIGNATURE**

**ENDORSEMENT OF THE RESEARCH REVIEW AUTHORITY (IF OUTSIDE COMMANDER'S DIRECT AUTHORITY)**