



DoD INSTRUCTION 3216.02

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

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Approved by:	Michael Griffin, Under Secretary of Defense for Research and Engineering

Purpose: In accordance with the authority in DoD Directive 5134.01, the July 13, 2018 Deputy Secretary of Defense Memorandum, 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).

(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).

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/>.

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.

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.

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.

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.

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.

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.

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.

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

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.

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

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

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

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 too the DOHRP, no fewer than 30 business days before beginning research involving LSGD collected from DoD-affiliated personnel.

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.

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

(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.

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

(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.

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

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

(f) Establish policy for designating human protections directors (HPDs), human research protection official(s) (HRPOs) and exemption determination officials (EDOs) to include specifying qualifications, training, and responsibilities.

(g) Establish policy and institutional requirements for managing allegations of, and reporting noncompliance with, federal regulations, State and local laws, Native American or Alaskan native tribal laws, foreign laws, and DoD issuances and policies.

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

(i) Establish policy and institutional requirements for managing conflicts of interest, including financial and non-financial interest conflicts, personal considerations, or perceptions of a possible conflict.

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

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

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

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

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.

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.

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

- c. Designate a HPD as the primary point of contact for the institution's HRPP.
- d. As applicable, identify an IO to establish and maintain a DoD assurance and other appropriate assurances. An alternate IO (AIO) may be appointed.
- e. Evaluate and improve the institution's HRPP, its policies, and its standard operating procedures.
- f. Establish a program of post-approval compliance monitoring of HSR conducted or supported by the institution.

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.

(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.

(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.

(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.

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

(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.

(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.

(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.

(b) The research requires a waiver of informed consent pursuant to Subsection (b) of Section 980 of Title 10, U.S.C.

(c) The research is fetal research, as described in Sections 289g–289g-2 of Title 42, U.S.C.

(d) LSGD is collected from DoD-affiliated personnel.

(e) The research constitutes classified HSR as defined by this issuance.

(f) Research is required to be approved by the DOHRP.

(2) DoD administrative and DoD Component security reviews must be conducted before research involving LSGD collected from DoD-affiliated personnel may begin.

(3) The DoD Component may, with DOHRP approval, delegate Component review and oversight of Sections 3.5.b.(1)(a) - (f) to a DoD institution.

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.

(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.

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.

(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.

(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.

(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.

(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.

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

3. IRB-approved protocol documents.

4. Current FWA and IRB registration numbers.

(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.

(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.

10. Will recognize that failure to comply with applicable requirements may result in the DoD:

a. Wholly or partially terminating or suspending the award;

b. Temporarily withholding payment under the award pending correction of the deficiency;

c. Disallowing all or part of the cost of the activity or action that is not in compliance; and/or

d. Contacting publishers of articles that reference the noncompliant HSR.

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

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).

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.

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.

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.

(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.

3.10. RESEARCH INVOLVING LSGD COLLECTED ON DOD-AFFILIATED 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.

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.

(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.

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.

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.

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.

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.

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.

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

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.

GLOSSARY

G.1. ACRONYMS.

ACRONYM	MEANING
AIO	alternate institutional official
CCHRPP	Coordinating Committee for Human Research Protection Programs
CFR	Code of Federal Regulations
CLAR	component-level administrative review
CMP	component human research protection program management plan
CoC	certificate of confidentiality
COHRP	component office of human research protections
DC	DoD Office for Human Research Protections Cabinet
DFARS	Defense Federal Acquisition Regulation Supplement
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
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 institutional review board review
IO	institutional official
IRB	institutional review board
LSGD	large-scale genomic data
SDO	senior designated official
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.
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 Defense, including subordinate agencies heads who have been delegated authority to study, evaluate, improve, or otherwise assess DoD performance, quality, and capability.
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.
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.
DoD institution	A DoD entity which conducts activities that may be HSR.

TERM

DEFINITION

excluded activities

The following activities conducted or supported by the DoD are not considered HSR:

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.

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.

Activities performed for the sole purpose of medical quality assurance (see Section 1102 of Title 10, U.S.C., and DoDI 6025.13).

Activities that meet the definition of operational test and evaluation as defined in Section 139(a)(2)(A) of Title 10, U.S.C.

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.

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 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.

TERM	DEFINITION
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.
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	<p>A living individual about whom an investigator (whether professional or student) conducting research:</p> <p>Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or</p> <p>Obtains, uses, studies, analyzes, or generates identifiable private information, personally identifiable information, or identifiable biospecimens.</p>

TERM	DEFINITION
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.
intervention	Includes both physical procedures by which information or biospecimens are gathered (<i>e.g.</i> , 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.
key investigator	The person leading the performance of research.
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.
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.

TERM	DEFINITION
protocol	<p>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.</p>
research	<p>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:</p> <p>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.</p> <p>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).</p> <p>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.</p> <p>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.</p>

TERM	DEFINITION
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 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.
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.
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.
support	<p>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.</p> <p>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.</p> <p>This definition does not include DoD-conducted HSR, whether or not conducted in collaboration between a DoD institution and non-DoD institution.</p>

REFERENCES

- 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
- 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 6055.18-M, “Safety Standards for Microbiological and Biomedical Laboratories,” May 11, 2010, as amended
- DoD 5240.1-R, “Procedures Governing the Activities of DoD Intelligence Components that Affect United States Persons” December 1982, as amended
- DoD Directive 2310.01E, “DoD Detainee Program,” August 19, 2014
- DoD Directive 5134.01, “Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L)),” December 9, 2005, as amended
- DoD Instruction 1100.13, “DoD Surveys,” January 15, 2015, as amended
- 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 Secretarial Designee 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
- 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 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
- Executive Order 12333, “United States Intelligence Activities,” as amended, August 18, 2010
- 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

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

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

United States Code, Title 10

United States Code, Title 24, Section 30

United States Code, Title 42

United States Code, Title 5

United States Code, Title 50, Section 1520a