



INVESTIGATOR GUIDANCE: Additional DOD Obligations

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1. PURPOSE

- 1.1. This guidance outlines the additional obligations of investigators conducting research supported or conducted by DOD.

2. GUIDANCE

- 2.1. The following activities conducted or supported by the DoD are not considered human subject research:
 - 2.1.1. 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.
 - 2.1.2. 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.
 - 2.1.3. Activities performed for the sole purpose of medical quality assurance (see Section 1102 of Title 10, U.S.C., and DoDI 6025.13).
 - 2.1.4. Activities that meet the definition of operational test and evaluation as defined in Section 139(a)(2)(A) of Title 10, U.S.C.
 - 2.1.5. 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.
 - 2.1.6. 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.
- 2.2. This guidance applies to:
 - 2.2.1. 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").
 - 2.2.2. DOD Components and other organizational entities that issue, implement, update, and monitor a component human research protection program (HRPP) management plan (component human research protection program management plan) 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.
 - 2.2.3. Human subject research (human subject research) conducted or supported by the DOD (for DOD exclusions, see Glossary).
 - 2.2.4. 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).
- 2.3. This guidance'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 (Under



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Secretary of Defense for Research and Engineering DOD Office for Human Research Protections (DOD Office for Human Research Protections) website <https://rt.cto.mil/ddre-rt/dd-rtl/hsd/hrp/>.

2.4. The DOD will:

- 2.4.1. 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.
- 2.4.2. 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.
- 2.4.3. Recognize and adhere to Subpart E in Part 46 of Title 45, CFR.
- 2.4.4. Prohibit human subject research 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 human subject research can begin, the DOD Component seeking to conduct the human subject research must receive explicit written approval from the DOD Office for Human Research Protections. The DOD Office for Human Research Protections 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.
- 2.4.5. 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.
- 2.4.6. Conduct and support human subject research outside of the United States in accordance with federal and DOD regulatory requirements and the host nation's laws, as applicable. Host nation human subject research 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 human subject research laws will be applicable. DOD Components conducting and supporting human subject research outside of the United States will consult with legal counsel, on a case-by-case basis, to determine whether host nation human subject research laws are applicable. Where differences in applicable standards exist, the standard that is most protective of human subjects will be applied.
- 2.4.7. 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 human subject research that is to be conducted or supported in their area of responsibility before human subject research proceeds. This does not apply to research performed within the United States or at DOD institutions overseas.
- 2.4.8. Require research involving large-scale genomic data (large-scale genomic data) collected from DOD-affiliated personnel to be subject to DOD Component security review and DOD Office for Human Research Protections approval, including the secondary use or sharing of de-identified data or specimens.
- 2.4.9. 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 DOD Office for Human Research Protections guidance and with DOD Component notification to the DOD Office for Human Research Protections that a DOD institution intends to use broad consent in a research protocol.

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- 2.4.10. 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 (component human research protection program management plan) 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 human subject research. Studies already in progress before January 20, 2020, will not be required to transition to a single IRB, nor submit exception documentation.
 - 2.4.11. Recognize that component human research protection program management plans 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.
 - 2.4.12. Recognize that certain activities subject to this issuance are excluded from the requirements outlined in DOD Instruction (DOD instruction) 8910.01, Volumes 1 and 2 of DOD Manual 8910.01, and DOD instruction 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.
- 2.5. Under Secretary of Defense for Research and Engineering
- 2.5.1. Is the:
 - 2.5.1.1. DOD point of contact for all matters related to DOD compliance with this issuance.
 - 2.5.1.2. Principal DOD liaison with agencies and organizations outside the DOD on matters pertaining to human subject research, including ethics and privacy concerns in research as they relate to human subject research.
 - 2.5.2. Provides procedures and guidance necessary to implement this issuance.
 - 2.5.3. Exercises:
 - 2.5.3.1. The authorities of:
 - 2.5.3.1.1. The department head identified in Part 219 of Title 32, CFR.
 - 2.5.3.1.2. The Secretary of Defense identified in Section 980 of Title 10, U.S.C.
 - 2.5.3.1.3. The Secretary of Defense for Subparts B-E of Part 46 of Title 45, CFR.
 - 2.5.3.2. The authority, direction, and control of the DOD Office for Human Research Protections to:
 - 2.5.3.2.1. Halt studies and rescind or limit authorities granted to DOD Components' HRPPs, as needed.
 - 2.5.3.2.2. Accept and approve each DOD Component's component human research protection program management plan, implementing and supporting policies or any modifications thereto, and provide oversight of the plan's implementation for compliance with this issuance. A DOD Office for Human Research Protections-approved component human research protection program management plan must be in place before DOD Components conduct or support any research involving human participants. The direct oversight

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of the DOD Component's implementation of its component human research protection program management plan and subsequent HRPP is with the DOD Office for Human Research Protections.

- 2.5.3.2.3. Establish guidance for:
 - 2.5.3.2.3.1. DOD Component human subject protection training.
 - 2.5.3.2.3.2. DOD Component security review of research involving large-scale genomic data collected on DOD-affiliated personnel, to include administrative, technical, and physical safeguards for protecting their confidentiality both during and after the conduction of research.
 - 2.5.3.2.3.3. DOD Component review of the ethical, legal, and social implications of emerging, readily available technologies or controversial research, development, testing, and evaluation.
 - 2.5.3.2.3.4. Mandatory submittal document for all DOD-supported human subject research.
- 2.5.3.2.4. 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.
- 2.5.4. Grants exceptions, consistent with law, to requirements in this issuance based on a written, appropriate justification from the senior designated official (senior designated official).
- 2.5.5. Delegates DOD Office for Human Research Protections authorities as appropriate.
- 2.5.6. Provides procedures in accordance with this issuance for use of certificates of confidentiality.
- 2.5.7. Designates DOD representatives to federal committees as appropriate.
- 2.5.8. Establishes and coordinates the activities of the DOD Coordinating Committee for HRPPs (Coordinating Committee for Human Research Protection Programs), along with its Executive Secretariat, the DOD Office for Human Research Protections Cabinet (DOD Office for Human Research Protections Cabinet). The DOD Office for Human Research Protections Cabinet is the central advisory body to the DOD, Under Secretary of Defense for Research and Engineering, and the DOD Office for Human Research Protections on matters outlined in this issuance.
- 2.5.9. Conducts Component HRPP assessments every other year.
- 2.5.10. Maintains:
 - 2.5.10.1. A list of classified human subject research.
 - 2.5.10.2. Lists of DOD IRBs and DOD Institutional Biosafety Committees.
- 2.5.11. Designates:
 - 2.5.11.1. The Director, Human Systems Directorate, who chairs the Coordinating Committee for Human Research Protection Programs and oversees the Director, DOD Office for Human Research Protections.
 - 2.5.11.2. The Director, DOD Office for Human Research Protections the authority for the operations of the DOD Office for Human Research Protections, and the designated manager for this issuance.
- 2.6. The heads of DOD Components that conduct or support human subject research:



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- 2.6.1. Issue, implement, update, and monitor the component human research protection program management plan for implementing this issuance and guidance or memoranda pursuant to this issuance.
- 2.6.2. Identify the senior designated official, 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 component human research protection program management plan.
- 2.6.3. Establish a component human research protection program management plan with authority and responsibility for the component human research protection program management plan and regulatory oversight of Component human subject research at its office and its institutions.
- 2.6.4. 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 component human research protection program management plan and subsequent HRPP. This individual's experience in DOD-conducted and DOD-supported human subject research, staff management, and systems of record must be commensurate with the scope of the HRPP.
- 2.6.5. Provide members to intra- and interagency committees, the Coordinating Committee for Human Research Protection Programs, and the DOD Office for Human Research Protections Cabinet when requested.
- 2.6.6. Require that all Component institutions and sub-institutions that conduct or support human subject research have a Component-approved HRPP.
- 2.6.7. Provide an index of all DOD-conducted or DOD-supported human subject research to the DOD Office for Human Research Protections before the end of each fiscal year.
- 2.7. The senior designated official of a DOD Component that conducts or supports human subject research:
 - 2.7.1. Will provide to the DOD Office for Human Research Protections, through the component human research protection program management plan, 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.
 - 2.7.2. Will provide to the DOD Office for Human Research Protections, through the component human research protection program management plan, copies of waivers to this issuance granted to a component human research protection program management plan on behalf of the senior designated official, if given the authority by the DOD Office for Human Research Protections, 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).
 - 2.7.3. Will provide to the DOD Office for Human Research Protections, through the component human research protection program management plan, approvals and documentation of human subject research in fetal research as described in Sections 289g–289g-2 of Title 42, U.S.C. The senior designated official must obtain written approval from the DOD Office for Human Research Protections before human subject research activities involving fetal research may begin.
 - 2.7.4. Will provide to the DOD Office for Human Research Protections, through the component office of human research protections, approvals and documentation of protocols requiring certification from the senior designated official 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



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problem affecting the health or welfare of pregnant women, fetuses, or neonates. The senior designated official must obtain written approval from the DOD Office for Human Research Protections before permitting any human subject research 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.

- 2.7.5. Will provide to the DOD Office for Human Research Protections, through the component human research protection program management plan, approvals of human subject research 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 human subject research.
 - 2.7.6. Will provide to the DOD Office for Human Research Protections, through the component human research protection program management plan, reports of for-cause audits, reviews, or assessments conducted by or on behalf of the component human research protection program management plan within 5 business days of writing the document.
 - 2.7.7. Will provide to the DOD Office for Human Research Protections, through the component human research protection program management plan, reports of audits of DOD-conducted or DOD-supported human subject research 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.
 - 2.7.8. Will provide to the DOD Office for Human Research Protections, through the component human research protection program management plan, reports required in accordance with Title 32, CFR, or similar reports upon request by the DOD Office for Human Research Protections, within 5 business days of the report's completion, pertaining to:
 - 2.7.8.1. Allegations of serious or continuing noncompliance related to human subject research that are substantiated by investigation, and subsequent actions taken based on the findings;
 - 2.7.8.2. Unanticipated problems involving risks to human subjects or others and subsequent actions taken based on the findings; or
 - 2.7.8.3. Suspensions or terminations of IRB approval.
 - 2.7.9. Will submit written justification to the DOD Office for Human Research Protections to establish a new IRB, or substantially modify an IRB, at a minimum of 120 business days before establishment or modification for DOD Office for Human Research Protections concurrence. Will notify the DOD Office for Human Research Protections at least 120 business days before disestablishing an IRB.
 - 2.7.10. Will provide details of DOD Component security reviews too the DOD Office for Human Research Protections, no fewer than 30 business days before beginning research involving large-scale genomic data collected from DOD-affiliated personnel.
- 2.8. component human research protection program management plan
- 2.8.1. The component human research protection program management plan must:
 - 2.8.1.1. Include or reference DOD Component policies to implement this issuance and identify the responsible DOD Component office(s) for actions identified in this issuance.
 - 2.8.1.2. Identify the senior designated official with the authority and responsibility for implementing the component human research protection program management plan.



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- 2.8.1.3. Be consistent with DOD Office for Human Research Protections guidance and include or reference DOD Component policies and procedures, if applicable, that:
- 2.8.1.3.1. Establish authority for, and include or reference policies under which, the component human research protection program management plan will issue, limit, or revoke DOD assurances upon assessment of institutions' HRPPs.
 - 2.8.1.3.2. Describe the DOD Component's program or provisions for exercising authorities delegated from the DOD Office for Human Research Protections to the senior designated official.
 - 2.8.1.3.3. Describe, consistent with DOD Office for Human Research Protections guidance, the DOD Component's implementation of security review of research involving large-scale genomic data collected from DOD-affiliated personnel and procedures to obtain senior designated official and DOD Office for Human Research Protections approval.
 - 2.8.1.3.4. Establish DOD Component and institutional requirements for human subject protection training.
 - 2.8.1.3.5. Establish procedures for certification in accordance with Part 219 of Title 32, CFR.
 - 2.8.1.3.6. Establish policy for designating human protections directors (human protections directors), human research protection official(s) (human research protection officials) and exemption determination officials to include specifying qualifications, training, and responsibilities.
 - 2.8.1.3.7. 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.
 - 2.8.1.3.8. Establish DOD Component and institutional responsibilities for required reporting to the DOD Office for Human Research Protections, including reports pursuant to Title 32, CFR.
 - 2.8.1.3.9. 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.
 - 2.8.1.3.10. Establish policy for the maintenance of human subject research records, including records and workflows maintained in electronic form, required by governing regulations and this issuance.
 - 2.8.1.3.11. Establish policy in accordance with DOD instruction 6025.23 for addressing subjects' research-related injuries in DOD-conducted research.
 - 2.8.1.3.12. Establish policy and institutional requirements for human research protection official review of DOD-supported human subject research conducted by non-DOD institutions.
 - 2.8.1.3.13. Establish policy and institutional requirements for administrative review of DOD-supported and DOD-conducted human subject research performed by DOD and non-DOD institutions.

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- 2.8.2. Required component human research protection program management plan elements may be modified upon waiver request by the component human research protection program management plan or the prospective component human research protection program management plan on behalf of the senior designated official for DOD Office for Human Research Protections approval.
- 2.8.3. A DOD Component may, in a written arrangement approved by the DOD Office for Human Research Protections, rely on another DOD Component to implement elements of the relying DOD Component's component human research protection program management plan, except for designating the relying DOD Component's senior designated official. The DOD Component relying on another DOD Component to implement elements of its component human research protection program management plan must specify the existence and extent of any such reliance in its component human research protection program management plan.
- 2.9. Under the authority, direction, and control of the senior designated official in the DOD Component, each commander or director of a DOD institution that conducts or supports human subject research must:
 - 2.9.1. Establish, implement, and maintain an HRPP to ensure the institution's compliance with this issuance.
 - 2.9.2. Provide experienced, well-qualified HRPP staff and appropriate resources needed to ensure compliance with this issuance.
 - 2.9.3. Designate a human protections director as the primary point of contact for the institution's HRPP.
 - 2.9.4. As applicable, identify an IO to establish and maintain a DOD assurance and other appropriate assurances. An alternate IO (Alternate Institutional Official) may be appointed.
 - 2.9.5. Evaluate and improve the institution's HRPP, its policies, and its standard operating procedures.
 - 2.9.6. Establish a program of post-approval compliance monitoring of human subject research conducted or supported by the institution.
- 2.10. FEDERAL ASSURANCE.
 - 2.10.1. When a Federal Assurance Is Required.
 - 2.10.1.1. A DOD institution conducting non-exempt human subject research must have a DOD assurance for the protection of human subjects. All DOD assurances must be executed using templates approved by the DOD Office for Human Research Protections. 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 DOD Office for Human Research Protections.
 - 2.10.1.2. 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 human subject research supported by HHS.
 - 2.10.1.3. A non-DOD institution must rely on an FWA, or a comparable federal assurance, when engaged in non-exempt DOD-supported human subject research.
 - 2.10.1.4. Researchers affiliated with institutions that do not hold a federal assurance may enter into individual investigator agreements (individual investigator agreement) to associate with an institution with a federal assurance. All researchers conducting non-exempt human subject research must be covered by their own institution's federal assurance or by another institution's federal assurance through an individual investigator agreement.



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- 2.10.1.5. 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.
- 2.10.1.6. 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 human protections director as the primary contact for the institution's HRPP.
- 2.10.1.7. DOD institutions and all non-DOD institutions conducting human subject research 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.
- 2.10.2. When a Federal Assurance Is Not Required.
 - 2.10.2.1. A federal assurance is not required when an institution's role is limited to the conduct or support of exempt human subject research or activities determined by designated HRPP personnel to be research not involving human subjects.
 - 2.10.2.2. DOD institutions that only support human subject research conducted by an institution with an assurance, also known as an assured institution, are not required to maintain their own federal assurance.
- 2.11. DOD-CONDUCTED RESEARCH.
 - 2.11.1. DOD Institutional Approval and Oversight.
 - 2.11.1.1. DOD institutions must have policies and procedures to ensure that all applicable human subject research approvals are in place before human subject research begins.
 - 2.11.1.2. A DOD IO or Alternate Institutional Official, 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.
 - 2.11.1.3. A DOD IO or Alternate Institutional Official, 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 Alternate Institutional Official must be given approval by the component human research protection program management plan, on behalf of the senior designated official, to have the ability to establish such agreements.
 - 2.11.1.4. DOD IRBs must comply with Section 219.107 of Title 32, CFR.
 - 2.11.1.5. DOD IRBs will document their consideration of scientific merit; within the consideration of scientific merit, feasibility of study completion should be considered.
 - 2.11.1.6. If the human subject research 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 human subject research takes place on a DOD facility, the key investigator must also receive approval from the command or DOD Component responsible for the facility.



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- 2.11.1.7. Only designated federal DOD HRPP personnel are authorized to make determinations regarding whether or not an activity is human subject research or is exempt human subject research.
- 2.11.1.8. DOD institutions collaborating in human subject research with non-DOD institutions may rely on the collaborating non-DOD institution's IRB if all of the following conditions are met:
 - 2.11.1.8.1. The DOD institution determines the non-DOD institution has an appropriate federal assurance or that a federal assurance is not required.
 - 2.11.1.8.2. The non-DOD institution's IRB is registered in accordance with Subpart E of Part 46 of Title 45, CFR.
 - 2.11.1.8.3. The DOD institution reviews the protocol to ensure all applicable local and DOD requirements are addressed in the protocol.
 - 2.11.1.8.4. 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.
 - 2.11.1.8.5. If the research constitutes classified human subject research, the component human research protection program management plan, on behalf of the senior designated official, approves the agreement to rely on the non-DOD institution's IRB.
- 2.11.1.9. DOD institutions conducting human subject research in collaboration with non-DOD institutions with or without DOD support must comply with all requirements in this issuance pertaining to DOD-conducted research.
- 2.11.2. DOD Component Administrative Review and Oversight.
 - 2.11.2.1. The DOD Component must conduct an administrative review (also known as a component-level administrative review (component-level administrative review)) of all non-exempt human subject research when any of the following conditions occur:
 - 2.11.2.1.1. Human subject research is conducted in a foreign country, unless conducted by a DOD overseas institution, or only involves DOD-affiliated personnel who are U.S. citizens.
 - 2.11.2.1.2. The research requires a waiver of informed consent pursuant to Subsection (b) of Section 980 of Title 10, U.S.C.
 - 2.11.2.1.3. The research is fetal research, as described in Sections 289g-289g-2 of Title 42, U.S.C.
 - 2.11.2.1.4. large-scale genomic data is collected from DOD-affiliated personnel.
 - 2.11.2.1.5. The research constitutes classified human subject research as defined by this issuance.
 - 2.11.2.1.6. Research is required to be approved by the DOD Office for Human Research Protections
 - 2.11.2.2. DOD administrative and DOD Component security reviews must be conducted before research involving large-scale genomic data collected from DOD-affiliated personnel may begin.
 - 2.11.2.3. The DOD Component may, with DOD Office for Human Research Protections approval, delegate Component review and oversight of Sections 3.5.b.(1)(a) - (f) to a DOD institution.

2.12. DOD-SUPPORTED RESEARCH



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- 2.12.1. DOD Component Approval and Oversight.
 - 2.12.1.1. The DOD Component must conduct a component-level administrative review of all non-exempt human subject research when any of the following conditions occur:
 - 2.12.1.1.1. 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.
 - 2.12.1.1.2. The research requires a waiver of informed consent pursuant to Paragraph (b) of Section 980 of Title 10, U.S.C.
 - 2.12.1.1.3. The research is fetal research as described in Sections 289g–289g-2 of Title 42, U.S.C.
 - 2.12.1.1.4. large-scale genomic data is collected from DOD-affiliated personnel.
 - 2.12.1.1.5. The research constitutes classified human subject research as defined by this issuance.
 - 2.12.1.1.6. Research is required to be approved by the DOD Office for Human Research Protections.
 - 2.12.1.2. DOD administrative and DOD Component security reviews must be conducted before research involving large-scale genomic data collected from DOD-affiliated personnel may begin.
 - 2.12.1.3. The DOD Component may, with DOD Office for Human Research Protections approval, delegate DOD Component review and oversight of Sections 3.5.b.(1)(a) - (f) to a DOD institution.
- 2.12.2. DOD institutions planning to support human subject research must comply with the requirements in this paragraph, as applicable.
 - 2.12.2.1. Support for activities including research involving human subjects must consider Defense Federal Acquisition Regulation Supplement (Defense Federal Acquisition Regulation Supplement) Section 207.172 requirements as part of the acquisition planning process. All Federal Acquisition Regulation (Federal Acquisition Regulation)–based contracts for DOD-supported research that include or may include human subject research must contain the Defense Federal Acquisition Regulation Supplement clause 252.235-7004 in its entirety in accordance with Defense Federal Acquisition Regulation Supplement Section 235.072(e).
 - 2.12.2.1.1. All solicitations, including broad agency announcements, for DOD-supported research that include or may include human subject research must contain the Defense Federal Acquisition Regulation Supplement clause 252.235-7004, if the solicitation is for a Federal Acquisition Regulation-based contract or substantially similar language if the solicitation is for a non-Federal Acquisition Regulation-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 human research protection official is described in these two directives.
 - 2.12.2.1.2. Agreements other than contracts that include or may include human subject research, but are not subject to Defense Federal Acquisition Regulation Supplement clause

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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.

- 2.12.2.2. Contracts and other agreements (e.g., grants, assistance agreements) must:
- 2.12.2.2.1. Restrict the performance of prospective DOD-supported human subject research before the human research protection official's concurrence is provided.
 - 2.12.2.2.2. Be awarded before an official human research protection official review is provided, although a non-binding human research protection official review may be conducted before award.
 - 2.12.2.3. DOD institutions must appoint or designate human research protection official(s) to confirm that DOD-supported human subject research complies with this issuance.
 - 2.12.2.4. Defense Federal Acquisition Regulation Supplement clause 252.235-7004 is not required to be included in a DOD agreement with another federal agency for DOD-supported human subject research. 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.
 - 2.12.2.5. When a DOD IRB serves as the reviewing IRB pursuant to Part 219 of Title 32, CFR, the DOD IRB approval will constitute the human research protection official review; an additional human research protection official review is not required.
 - 2.12.2.6. The non-DOD institution:
 - 2.12.2.6.1. For non-exempt human subject research, must submit to the human research protection official:
 - 2.12.2.6.1.1. Documentation that the DOD-supported human subject research has been reviewed and approved by an IRB, including scientific merit, amendments, and additional reviews.
 - 2.12.2.6.1.2. Documentation of key investigators' human research protection training.
 - 2.12.2.6.1.3. IRB-approved protocol documents.
 - 2.12.2.6.1.4. Current FWA and IRB registration numbers.
 - 2.12.2.6.2. 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 human subject research, exempt human subject research, or limited IRB review to the human research protection official, to include all protocol documents.
 - 2.12.2.6.3. Must comply with all reporting requirements that may otherwise be applicable, in addition to the human research protection official reporting and submission requirements in this section.
 - 2.12.2.6.4. Must promptly notify the human research protection official of the following:

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- 2.12.2.6.4.1. IRB-approved changes to human subject research 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.
- 2.12.2.6.4.2. Transfer of human subject research oversight to a different IRB.
- 2.12.2.6.4.3. 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 human subject research is under investigation.
- 2.12.2.6.4.4. Any problems involving risks to subjects or others, suspension or termination of IRB approval, or any serious or continuing noncompliance pertaining to DOD-supported human subject research.
- 2.12.2.6.4.5. The results of the IRB's continuing review, if required.
- 2.12.2.6.4.6. 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.
- 2.12.2.6.4.7. 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.
- 2.12.2.6.4.8. A DOD-supported study's closure.
- 2.12.2.6.4.9. 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.
- 2.12.2.6.4.10. Will recognize that failure to comply with applicable requirements may result in the DOD: Wholly or partially terminating or suspending the award; Temporarily withholding payment under the award pending correction of the deficiency; Disallowing all or part of the cost of the activity or action that is not in compliance; and/or Contacting publishers of articles that reference the noncompliant human subject research.
- 2.12.2.6.4.11. Will recognize that DOD-supported research should comply with the whole of this issuance when applicable.

2.13. DOD-ASSISTED RESEARCH.

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2.13.1. Each component human research protection program management plan 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 human subject research when the DOD support is limited to assistance (as defined in this issuance).

2.14. SELECTION OF HUMAN SUBJECTS AND EVALUATING RISK.

2.14.1. The selection of human subjects in DOD-conducted or DOD-supported human subject research 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 component human research protection program management plan.

2.14.2. 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:

2.14.2.1. Encountered by Service members, law enforcement, or first responders while on duty.

2.14.2.2. Resulting from or associated with high-risk behaviors or pursuits.

2.14.2.3. Experienced by individuals whose medical conditions involve frequent tests or constant pain.

2.15. ADDITIONAL PROTECTIONS FOR HUMAN SUBJECTS.

2.15.1. 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.

2.15.1.1. The additional safeguards set forth in Sections 3.9(b)-(f) must be provided in DOD-conducted and DOD-supported human subject research.

2.15.1.2. The DOD Office for Human Research Protections may delegate the authority for implementation of Subparts B, C, and D of Part 46 of Title 45, CFR, to the DOD Components' senior designated officials within their component human research protection program management plan.

2.15.2. 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.

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

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

2.15.2.2.1. The woman or the fetus; or

2.15.2.2.2. Fetuses or neonates as human subjects.

2.15.2.3. Human subject research using fetal tissue must comply with Sections 289g-289g-2 of Title 42, U.S.C.

2.15.2.4. For human subject research that would not otherwise be approved but presents an opportunity to understand, prevent, or alleviate a serious

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problem affecting the health or welfare of pregnant women, fetuses, or neonates. DOD institutions must demonstrate to the senior designated official that the IRB has fulfilled its duties in accordance with Subpart B of Part 46, Title 45, CFR. Before human subject research activities may begin, the senior designated official must receive explicit written approval from the DOD Office for Human Research Protections.

- 2.15.3. Human subject research involving prisoners as human subjects must comply with Subpart C of Part 46 of Title 45, CFR, unless modified by this issuance.
 - 2.15.3.1. In addition to the categories of permissible human subject research involving prisoners identified in Subpart C of Part 46 of Title 45, CFR, two additional categories are permissible:
 - 2.15.3.1.1. 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.
 - 2.15.3.1.2. Human subject research 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.
 - 2.15.3.2. DOD institutions conducting research involving prisoners must demonstrate to the senior designated official that the IRB has fulfilled its duties in accordance with Subpart C of Part 46 of Title 45, CFR.
 - 2.15.3.3. 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 human protections director must notify the component human research protection program management plan. For DOD-supported research, the non-DOD institution must notify the human research protection official and other federal agencies, if required.
- 2.15.4. Human subject research involving children as human subjects must comply with Subpart D of Part 46 of Title 45, CFR. DOD institutions must demonstrate to the senior designated official 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.
- 2.15.5. Research involving a detainee or a prisoner of war as a human subject is prohibited.
 - 2.15.5.1. 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.
 - 2.15.5.2. 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.
- 2.15.6. DOD-affiliated Personnel as subjects in DOD-conducted or –supported human subject research.
 - 2.15.6.1. If the human subject research involves DOD-affiliated personnel as subjects and if the human subject research includes any risks to their

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fitness for duty (e.g. health, availability to perform job, data breach), the informed consent document (INFORMED CONSENT DOCUMENT) must inform DOD-affiliated personnel about these risks and that they should seek command or Component guidance before participating.

- 2.15.6.2. If the human subject research involves DOD-affiliated personnel, the key investigator must receive command or Component approval to execute the research.
- 2.15.6.3. Military and civilian supervisors, officers, and others in the chain of command are prohibited from influencing their subordinates to participate in human subject research.
- 2.15.6.4. Military and civilian supervisors, officers, and others in the chain of command must not be present at any human subject research participant recruitment sessions or during the human subject research consent process for DOD-affiliated personnel. Excluded supervisors or those in the chain of command may participate in separate human subject research recruitment sessions, if applicable.
- 2.15.6.5. 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 human subject research recruitment process and the necessity of including such member as a human subject.
- 2.15.6.6. In order to approve research involving DOD-affiliated personnel as human subjects, the IRB or human research protection official must determine whether the following requirements have been satisfied:
 - 2.15.6.6.1. The consent documentation must include, if applicable, potential risks for the revocation of clearance, credentials, or other privileged access or duty.
 - 2.15.6.6.2. For research involving recruitment of DOD-affiliated personnel in human subject research determined greater than minimal risk, as defined by Part 219 of Title 32, CFR, and when human subject research recruitment occurs in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:
 - 2.15.6.6.2.1. Must not have a conflict of interest with the research or be a part of the research team.
 - 2.15.6.6.2.2. Must be present during the human subject research 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.
 - 2.15.6.6.2.3. Should be available to address DOD-affiliated personnel's concerns about participation.
- 2.15.6.7. 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.

2.16. Research involving large-scale genomic data collected on DOD-affiliated personnel.

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- 2.16.1. DOD-conducted or DOD-supported research involving large-scale genomic data collected on DOD-affiliated personnel, or for which research the DOD provides assistance, is subject to additional requirements in this issuance.
 - 2.16.2. 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.
 - 2.16.3. All research involving large-scale genomic data collected from DOD-affiliated personnel will apply an HHS Certificate of confidentiality pursuant to Title 42, U.S.C., and Public Law 114-255.
 - 2.16.4. Research involving large-scale genomic data 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.
- 2.17. UNIQUE DOD LIMITATIONS ON WAIVER OF INFORMED CONSENT.
- 2.17.1. 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 human subject research.
 - 2.17.2. Section 980 of Title 10, U.S.C.:
 - 2.17.2.1. Imposes limitations on waiving informed consent when DOD appropriated funds are used to finance the research.
 - 2.17.2.2. 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.
 - 2.17.2.3. Is not applicable to exempt human subject research.
 - 2.17.3. 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.
 - 2.17.4. 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).
 - 2.17.5. The advance informed consent requirement pursuant to Section 980 of Title 10, U.S.C., may be waived by the DOD Office for Human Research Protections or its delegate, if the following conditions are met:
 - 2.17.5.1. The research is to advance the development of a medical product necessary to the DOD.
 - 2.17.5.2. The research may directly benefit the individual experimental subject.
 - 2.17.5.3. The research is conducted in compliance with all other applicable laws and regulations.
- 2.18. 3.12. PROTECTING HUMAN SUBJECTS FROM MEDICAL EXPENSES IF INJURED
- 2.18.1. DOD-Supported Research Involving Human Subjects.
 - 2.18.2. All non-exempt human subject research must meet the requirement in Section 219.116 of Title 32, CFR.

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- 2.18.3. DOD-Conducted Research Involving Human Subjects.
- 2.18.4. All human subject research 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.

- 2.18.4.1. 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.
- 2.18.4.2. 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.
- 2.18.4.3.) 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 DOD instruction 6025.23.

2.19. CLASSIFIED human subject research.

- 2.19.1. 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 human subject research is considered classified human subject research when:
 - 2.19.1.1. Classified information is required for IRB review and oversight of the research.
 - 2.19.1.2. Classified information must be provided to human subjects, or their guardians, during the human subject research recruitment or informed consent process in order to achieve fully effective legal consent.
 - 2.19.1.3. Classified information is provided to, or by, research subjects.
- 2.19.2. DOD-conducted or –supported human subject research is not considered classified human subject research:
 - 2.19.2.1. If the human subject research 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 human subject research that falls into the criteria listed in this paragraph should be included in the report.
 - 2.19.2.2. Human subject research 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 human subject research unless one of the conditions described in Sections 3.13.b.(1) or (3) also exist.
 - 2.19.2.3. If the research constitutes an authorized operational activity, then it is not human subject research.
- 2.19.3. The DOD Office for Human Research Protections is the final approval authority for all DOD-conducted or DOD-supported classified human subject research. The senior designated official prospectively conducting or supporting the human subject research must submit a package to the DOD Office for Human Research Protections for approval to conduct the classified human subject research.



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- 2.19.4. No DOD agency within the Intelligence Community may sponsor, contract for, or conduct non-exempt human subject research except in accordance with Paragraph 2.10 of Executive Order 12333 and DOD 5240.1.
- 2.20. There are certain authorities that the DOD Components may consider using for sensitive research.
 - 2.20.1. Confidential Information Protection and Statistical Efficiency Act for Non-Statistical Agencies.
 - 2.20.2. 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.
 - 2.20.3. A DOD institution conducting human subject research or non-DOD institution conducting human subject research with DOD support may request a Certificate of confidentiality pursuant to Section 241 of Title 42, U.S.C. All studies involving large-scale genomic data collected on DOD-affiliated personnel will apply an HHS Certificate of confidentiality.
 - 2.20.3.1. A Certificate of confidentiality 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.
 - 2.20.3.2. Exceptions to the Certificate of confidentiality must be listed in all informed consent documents, pursuant to this issuance and as stated in Section 241 of Title 42, U.S.C.
- 2.21. RECORD-KEEPING.
 - 2.21.1. Part 219 of Title 32, CFR, requires all institutions engaged in DOD-conducted or DOD-supported human subject research 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.
 - 2.21.2. For complete record-keeping guidance and instruction, DOD institutions must consult their records disposition schedules.
 - 2.21.3. 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
- 2.22. NONCOMPLIANCE.
 - 2.22.1. DOD institutions must promptly respond to allegations of noncompliance with this issuance.
 - 2.22.2. 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 human research protection official. The DOD institution supporting the human subject research 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 component human research protection program management plan.



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- 2.22.3. Substantiated allegations related to classified human subject research must be reported immediately to the DOD Office for Human Research Protections.
- 2.23. The Coordinating Committee for Human Research Protection Programs is composed of senior officials at the general officer/flag officer, Senior Executive Service, or equivalent level.
 - 2.23.1. Each senior designated official must identify one regular and one alternate member to represent their component to the Coordinating Committee for Human Research Protection Programs, and must promptly notify the DOD Office for Human Research Protections if those designations change.
 - 2.23.2. The Coordinating Committee for Human Research Protection Programs Chair is the Director, Human Systems Directorate, Office of the Under Secretary of Defense for Research and Engineering.
 - 2.23.3. The Executive Secretariat to the Coordinating Committee for Human Research Protection Programs is composed of the component human research protection program management plan directors, or equivalent authorities from the DOD Component HRPP oversight bodies, and those deemed necessary to the Executive Secretariat's missions by the DOD Office for Human Research Protections Director.
 - 2.23.3.1. The Executive Secretariat is referred to as the DOD Office for Human Research Protections Cabinet; its Chair is the Director, DOD Office for Human Research Protections.
 - 2.23.3.2. The DOD Office for Human Research Protections Cabinet acts as a central advisory committee to the DOD, the Under Secretary of Defense for Research and Engineering, and the DOD Office for Human Research Protections on matters regarding human subject research, privacy issues in research, ethical, legal and social implications in research.
 - 2.23.3.3. The DOD Office for Human Research Protections Cabinet may act as an ethics panel or body and designate subcommittees as needed.

3. REFERENCES

- 3.1. 10 USC 980
- 3.2. DOD Instruction 3216.02
- 3.3. DOD Instruction 3216.2
- 3.4. OPNAVINST 5300.8B
- 3.5. SECNAVINST 3900.39D

4. REVISION HISTORY

- 4.1. **Edition 004:** Extensive updates for revised DoD Instruction 3216.02
- 4.2. **Edition 003:** Move information about civilian researchers, add information about surveys across DOD components, change references to officers and non-commissions officers to superiors of service members, add reference to recruitment in a group setting.
- 4.3. **Edition 002:** Updates based on revised guidance