

**IRB Policy and Procedure**

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| **Wayne State University****Institutional Review Board** |
| **Subject** | **Department of Defense Requirements for Human Participant Research Protection (Policy 06-06)** |
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The purpose of this document is to provide guidance to Wayne State University (WSU) researchers whose human participants’ research involves any component of the Department of Defense (DoD).

**Background**

WSU has signed an Addendum to its Federal-wide Assurance (FWA) that it will apply DoD regulations and policies for the protection of human research participants when conducting, reviewing, approving, overseeing, supporting or managing human participants research involving the DoD.

The U.S. Department of Defense (DoD) is a signatory to the Common Rule with regulations equivalent to 45 CFR 46 published under [32 CFR 219](https://www.ecfr.gov/cgi-bin/text-idx?SID=a3c54b13da1439a7a68abb225d1d5d85&mc=true&node=se32.2.219_1102&rgn=div8). Research conducted or supported by DoD is subject to additional requirements for investigators and for reviewing IRBs. These requirements are outlined in this policy.

DoD support of a study includes funds or assistance by the DoD through a grant, contract, or similar agreement, and includes provision of assistance 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.

The Wayne State University IRB will review DoD research in accordance with the Common Rule (at [32 CFR 219](https://www.ecfr.gov/cgi-bin/text-idx?SID=a3c54b13da1439a7a68abb225d1d5d85&mc=true&node=se32.2.219_1102&rgn=div8)) and applicable DoD requirements, including:

* [DoD Instruction (DoDI) 3216.02](https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf), “Protection of Human Participants and Adherence to Ethical Standards in DoD-supported Research”;
* Subparts B, C, and D of 45 CFR 46 with modifications as described in DoDI 3216.02 (see 3.0 below for details);
* Title 10 United States Code Section 980 ([10 U.S.C. 980](https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/html/USCODE-2011-title10-subtitleA-partII-chap49-sec980.htm)), “Limitation on Use of Humans as Experimental Participants”;
* [DoDI 3210.7](https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321007p.pdf), “Research Integrity and Misconduct”;
* [DoDI 6200.2](https://mrdc.amedd.army.mil/assets/docs/orp/irbo/12_DoD_6200.02_App_of_FDA_rules_to_DoD_FHP_programs.pdf), “Application of Food and Drug (FDA) Rules to Department of Defense Force Health Protection Programs”; and
* Secretary of Navy, SecNav Instruction 3900.39D.

WSU allows research involving experimental participants when conducted in accordance with the U.S. Armed Forces 10 USC 980 *“Limitation on use of humans as experimental subjects”*, as implemented by DoDI 3216.02, section 3.11 as described in this policy.

Responsibility for upholding DoD requirements for human participant research is shared between researchers and their teams, the Institutional Review Board, University administration, and DoD. Investigators are responsible for ensuring that all DoD requirements are met before initiating the research. IRB staff, chairs and members will use this policy, DoDD 3216.02, the DoD Reviewer Checklist, and any relevant DoD Component-specific instructions or materials to guide the IRB review and oversight of DoD research.

**Scope**

This information and guidance applies to all biomedical and social/behavioral research which includes human participants research and is involved with a DoD component, with the following exception: for human participants research that qualifies for exemption see the guidance below entitled “Researcher Responsibilities – DoD Funding.”

Research is considered to involve the DoD when:

* The research is funded by a component of DoD (e.g., a grant from the U.S. Army Corps of Engineers).
* The research involves cooperation, collaboration, or other type of agreement with a component of DoD (e.g., An Army Medical Laboratory will conduct malaria antigen detection tests for study).
* The research uses property, facilities, or assets of a component of DoD.
* The participant population will intentionally include personnel (military and/or civilian) from a component of DoD.

DoD policies and requirements do not apply when DoD personnel incidentally take part in research that is NOT supported by DoD, and DoD personnel are not an intended population of the research.

Research supported by the DoD and “involving a human being as an experimental participant” is subject to the Federal Policy for the protection of human participants in research, i.e., the Common Rule. However, because of the DoD culture, organizational structure, and population, DoD Directive 3216.02 lays out additional requirements that apply as well. In the case of human research sponsored by the Department of the Navy, Secretary of the Navy Instructions (SECNAVINST 3900.39D) apply.These requirements are designed to cover risks unique to DoD employees that differ from civilians both in the conduct of research and in participation in research (e.g., deployability, personal conduct standards, and duty to report certain personnel actions). The procedures outlined in this policy ensure that WSU research supported by the DoD complies with DoD regulations governing human research.

**Related IRB Policies:**

* 4-15 Document Retention for Research Protocols
* 4-17 External IRB & Reliance Agreements for Multi-Site Research
* 6-4 International Research
* 8-1 Research Involving Fetuses and Neonates
* 8-2 Vulnerable Participants: Children
* 8-4 Vulnerable Participants: Prisoners
* 9-1 Requirements of Informed Consent
* 9-4 Obtaining Permission from Legally Authorized Representatives or Family Members
* 11-6 Planned Emergency Research
* 13-1 Unanticipated Problems and Other Reportable Events
* 15-1 Identifying, Defining and Managing Non-Compliance in Human Research

**Definitions:**

**Department of Defense Addendum to DHHS Federal-wide Assurance**: An application to the Department of Defense attesting that WSU will comply with all relevant federal regulations, DoD Instructions and Directives and other relevant documents regarding the protection of human participants in research. The Addendum applies to research supported by the DoD, Air Force, Navy, Marine Corps, and other affiliated facilities. (Note: The Army does not use the mechanism of an Addendum. Additional Army requirements are managed through the contracting process.)

**Department of Defense Component**: The term *DoD component* refers collectively to the organizational entities with the DoD that are subject to the human participants protections laid out in Department of Defense Directive 3216.02. These entities include, but may not be limited to:

Navy, Office of Naval Research, Naval Academy, U.S. Naval Observatory, Army, U.S. Army Corps of Engineers, Military Academy (West Point), Air Force, Air Force Academy, Marines, Coast Guard, Coast Guard Academy, National Guard, Missile Defense Agency, Defense Advanced Research Projects Agency (DARPA), Pentagon Force Protection Agency, Defense Intelligence Agency, National Geospatial-Intelligence Agency, National Security Agency, National War College, and Tricare Health System.

**Federal-wide Assurance (FWA):** A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human participants and stipulates the procedures through which compliance will be achieved (Federal Policy 45 CFR 46.103).

**Large Scale Genomic Data (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 human participants research. 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.

***Minimal Risk:*** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The definition of minimal risk based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests” shall not be interpreted to include the inherent risks certain categories of human participants face in their everyday life. For example, the risks imposed in research involving human participants focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

***Research involving a human being as an experimental participant***: Per DoDI 3216.02, research involving a human being as an experimental participant is defined as “*An activity for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental participant is a subset of research involving human participants”*

* **Note**: This definition relates only to the application of 10 U.S.C. 980; it does not affect the application of the Common Rule at [32 CFR 219](https://www.ecfr.gov/cgi-bin/text-idx?SID=a3c54b13da1439a7a68abb225d1d5d85&mc=true&node=se32.2.219_1102&rgn=div8).

***Detainees & Prisoner of War***: Research involving persons considered prisoners of war (POW) (i.e., captured, detained, held under the control of DoD personnel) is prohibited. Refer to the definition of “prisoner of war” for the Department of Defense component granting the addendum.

***Legally Authorized Representative***: Per military law and DoD Directive, informed consent may be provided by a legally-authorized representative of participants if: (1) the participant lacks capacity due to age, condition, or other reason, to make a decision regarding consent to participate in the research AND (2) the IRB has determined that the research is intended to be beneficial to the individual participants. (See IRB Policy 9-4 Obtaining Permission from Legally Authorized Representatives or Family Members).

**Chemical agents:** A chemical substance that is intended for use in military operations to kill, seriously injure, or incapacitate a person through its physiological effects. Excluded from consideration are riot control agents, chemical herbicides, smoke, and flame. (Section 1520a of Title 50, United States Code (U.S.C.)).

**Biological agent:** Micro-organism (including bacteria, viruses, fungi, rickettsia, or protozoa), pathogen, or infectious substance, and any naturally occurring, bioengineered, or synthesized component of any such micro-organism, pathogen, or infectious substance, whatever its origin or method of production, that is capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; or deterioration of food, water, equipment, supplies, or materials of any kind; or deleterious alteration of the environment. (DoD Directive 5210.65)

# 1.0 IRB Policy

# Research supported by the DoD and involving a human being as an experimental participant (as defined above), is subject to the Federal Policy for the protection of human participants in research, the Common Rule in Subpart A of 45 CFR 46 under 32 CFR 219. WSU allows DoD supported research involving experimental participants accordance with 10 USC 980, as implemented by DoDI 3216.01, section 3.11. WSU shall apply additional requirements outlined in DoD Directive 3216.02 when human research is conducted or supported by a DoD component (an organizational entity within the DoD).

# The DoD applies the provisions in 45 CFR 46, Subparts B, C, and D for the protection of vulnerable classes of participants.

# The University’s Federal-wide Assurance (FWA) with the Department of Health and Human Services (DHHS), Office of Human Research Protection (OHRP) meets the DoD requirement that the University maintain a federal assurance of compliance. The University shall complete a DoD addendum to its FWA when human participant research is conducted or funded by the DoD. The DoD addendum outlines the unique DoD component requirements that are not specifically included in the FWA.

# When following DoD regulations:

# For purposes of applying Subpart B, the phrase “biomedical knowledge” shall be replaced with “generalizable knowledge”

# The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and included interventions or invasive procedures to the women or the fetus or involving fetuses or neonates as participants.

# Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.

# Research involving prisoners cannot be reviewed by the expedited procedure.

# When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum.

**1.1 Prohibited DoD Research:**

**1.1.1 Research involving Chemical or Biological Agents:** Human participants research for the testing of chemical or biological agents is prohibited with exceptions for certain prophylactic, protective, or other peaceful purposes. Exceptions from the prohibition for such research must receive explicit written approval from the DoD Office for Human Research Protections (DOHRP).

**1.1.2 Classified Research:** Per Wayne State University Code University Research policy section 2.41.01.140: Classified research, that is any research placed under restrictions that prevent it from being freely described and its results openly published in the traditional manner, shall be excluded. This provision may be waived in a national emergency, and then only in circumstances that require University participation. A sponsor, upon request, may have the privilege of reviewing a report of the results of an investigation prior to publication, but publication delays beyond 90 days are not acceptable. Additional details about this process is described in the Wayne State University policy titled: Requesting a Waiver for Restricted and Proprietary Research.

**1.1.2.1 DoD-conducted or supported human subjects research is considered classified research when:**

* Classified information is required for IRB review and oversight of the research.
* Classified information must be provided to human participants, or their guardians, during the recruitment or informed consent process in order to achieve fully effective legal consent..
* Classified information is provided to, or by, research participants.

**1.1.2.2 DoD-conducted or supported human participant research is not considered classified research under the following:**

* If the 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 participant is not classified.
* If the research constitutes an authorized operational activity per [32 CFR 219.102(l)(4)](https://www.ecfr.gov/cgi-bin/text-idx?SID=a3c54b13da1439a7a68abb225d1d5d85&mc=true&node=se32.2.219_1102&rgn=div8) (because it is deemed ‘Not Research’).
* Research that requires participants 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 participants research unless one of the conditions described in section 1.1.2.1 exists.

Under such national security circumstances, investigators who seek to engage in classified research must obtain special permission from WSU’s Institutional Official (IO) who will engage other appropriate organizational leaders in the decision-making process. Upon approval from the IO, classified research must adhere to the following DoD restrictions:

* Waivers of consent are prohibited for DoD classified research.
* No DoD agency within the Intelligence Community may sponsor, contract for, or conduct non-exempt human participants research except in accordance with Paragraph 2.10 of [Executive Order 12333](https://www.intelligence.senate.gov/laws/united-states-intelligence-activities) and [DoD 5240.1](https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/524001r.pdf).
* The DOHRP is the final approval authority for all DoD-conducted or supported classified human participant research. The Senior Designated Official (SDO) of the relevant DoD component must submit a package to the DOHRP for approval to conduct the classified human participant research before the research can commence.

**1.1.3 Captured or Detained Persons of War:** This prohibition does not apply to activities covered by the Investigational New Drug (IND) or Investigational Device Exemption (IDE) provisions of the FDA regulations at [Title 21, CFR](https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials), when the purpose is for diagnosis or treatment of a medical condition in a patient. Such treatment may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to FDA regulations and only when the same product may be available to DoD-affiliated personnel consistent with established medical practices.

### 2.0 Informed Consent/HIPAA Authorization

[10 U.S.C. 980](https://www.govinfo.gov/content/pkg/USCODE-2011-title10/html/USCODE-2011-title10-subtitleA-partII-chap49-sec980.htm)  addresses requirements related to informed consent, or the waiver thereof, for research supported by DoD funds that involve a human being as an experimental participant. When WSU investigators engage in non-exempt research involving a human being as an experimental participant that is supported or conducted by the DoD, informed consent must be obtained in advance from the experimental participant or their legally authorized representative (LAR) if the participant cannot consent. If consent is to be obtained from a LAR, the research must be intended to be beneficial to the participant.

* If the participant is unable to provide informed consent and consent will be obtained in advance from the participant’s legal representative, the research must be intended to benefit the individual participant.

See IRB Policies 9-1 Requirements of Informed Consent, & 9-4 Obtaining Permission from Legally Authorized Representatives or Family Members for more information.

#### 2.1 Additional Consent/Authorization Elements

When consent is to be obtained from participants in DoD-conducted or supported research, the following additional information should be provided to potential participants in the consent document when applicable unless the requirement is waived by the DoD:

* A statement that the DoD or DoD component is conducting or supporting the research.
* A statement that representatives of the DoD are authorized to review research records.
* If the research involves DoD-affiliated personnel as participants and includes any risks to their fitness for duty (e.g., health, availability to perform job, data breach), the consent must inform DoD-affiliated personnel about these risks and that they should seek Command or Component guidance before participating.
* If the research involves DoD-affiliated personnel as participants, the consent must include, if applicable, potential risks for the revocation of clearance, credentials, or other privileged access or duty.
* If a Certificate of Confidentiality (CoC) is in place, exceptions to the CoC must be listed.
* If the research involves greater than minimal risk and is conducted by the DoD, the explanation regarding the availability of compensation and medical treatments for research-related injuries must include a statement that participants 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 [32 CFR 108](https://www.govinfo.gov/app/details/CFR-2011-title32-vol1/CFR-2011-title32-vol1-part108). This eligibility for health care services extends beyond participants’ involvement in the study to such time after the study has ended.

When HIPAA authorization is to be obtained, the authorization should include a statement that protected health information may be disclosed to representatives of the DoD.

#### 2.2 Waivers and Alterations of Informed Consent

The requirement for advanced informed consent may be waived (e.g., for planned emergency research) by the DoD Office for Human Research Protections (DOHRP) or its delegate if the following conditions are met:

* The research is to advance the development of a medical product necessary to the DoD;
* The research may directly benefit the individual experimental participant; and
* The research is conducted in compliance with all other applicable laws and regulations.

See IRB Policy 11-3 Planned Emergency Research for additional information about the process for obtaining a waiver of consent under the conditions listed above.

All DoD supported research involving a waiver of consent must undergo Component-Level Administrative review.

If the research involves no more than minimal risk, the IRB may alter or waive other required elements of informed consent so long as it still preserves informed consent of the participant (i.e., the consent indicates the participant’s involvement in the research is completely voluntary and includes the requirement that the participant is informed of research risks).

**Note:** Waivers of consent are prohibited for DoD classified research.

# 3.0 Additional Protections for Vulnerable Participants:

#### 3.1 Pregnant Women, Fetuses, or Neonates as Participants

In addition to Subpart B of 45 CFR 46, fetal research conducted or supported by DoD must comply with [42 U.S.C 289g – 289g-2](https://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title42-section289g&num=0&saved=%7CKHRpdGxlOjQyIHNlY3Rpb246Mjg5Zy0xIGVkaXRpb246cHJlbGltKQ%3D%3D%7C%7C%7C0%7Cfalse%7Cprelim). Research or experimentation may not be conducted in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation:

* May enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or
* Will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

The risk standard must be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

Explicit written approval is required from the DOHRP before the research begins for research that would not otherwise be approvable under Subpart B but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

See IRB Policy 8-1 Research Involving Fetuses and Neonates for more information.

# 3.2 Prisoners:

In addition to the categories of permissible human participant research involving prisoners identified in Subpart C of 45 CFR 46, two additional categories are permissible:

* Epidemiological research is permitted under the following conditions:
	+ Where the sole purpose of the research is to describe the prevalence or incidence of a disease by identifying all cases, or study potential risk factor associations for a disease.
	+ The research presents no more than minimal risk.
	+ The research involves no more than inconvenience to the prisoner-participants.
	+ Prisoners are not a particular focus of the research.
* Human participant research involving prisoners that would otherwise meet exemption criteria may be conducted but must first be approved by an IRB/EC and meet the requirements of Subpart C and DoDI 3216.02.

DoD organizations conducting research involving prisoners must demonstrate to the senior designated official that the IRB/EC has fulfilled its duties in accordance with Subpart C.

When a previously enrolled human participant becomes a prisoner, and the protocol has not been reviewed and approved by the IRB/EC in accordance with Subpart C, the researcher must promptly notify the IRB/EC.

* For DoD-conducted research, the human protections director must notify the COHRP.
* For DoD-supported research, the non-DoD organization must notify the DOHRP and other federal agencies.
* The DOHRP must concur with the IRB/EC before the participant can continue to participate while a prisoner.

# Please see IRB Policy IRB policy 8-4 Vulnerable Participants: Prisoners for more information.

# 3.3 Research Involving a Detainee or a Prisoner of War:

# Research involving a detainee or a prisoner of war as a human participant is prohibited. This prohibition does not apply under the following circumstances only:

* This prohibition does not apply to activities covered by investigational new drug or investigational device provisions of FDA regulations, when the purpose is for diagnosis or treatment of a medical condition in a patient.
* Such treatment may be offered to detainees or prisoners of war with their informed consent when the medical products are participant to FDA regulations, and only when the same product may be available to DoD-affiliated personnel consistent with established medical practices.

# 3.3 Children as Research Participants:

Research involving children as participants must meet the requirements of [Subpart D](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html) of 45 CFR 46 and [21 CFR 50.54](https://www.ecfr.gov/cgi-bin/text-idx?SID=31042205817afb0b7dcd59f9bbab69c4&mc=true&node=pt21.1.50&rgn=div5#sp21.1.50.d), if applicable. For more information, see IRB Policy 8-2 Vulnerable Participants: Children .

#### 3.4 DoD-Affiliated Personnel as Participants:

Service members and DoD-affiliated personnel (i.e., Service members, Reserve Service members, National Guard members, DoD civilians, and DoD contractors) are considered to be vulnerable to coercion and undue influence by the DoD due to the nature of the command structure of the organization.

The recruitment and inclusion of DoD-affiliated personnel must be approached with care and in accordance with the requirements of DoDI 3216.02 and any applicable DoD-component requirements.

Therefore, additional protections for DoD-affiliated personnel are required as follows pursuant to DoDI 3216.02 section 3.9(f)

* If the research involves DoD-affiliated personnel as participants, and the research includes any risks to their fitness for duty (e.g., health, availability to perform job, data breach), the informed consent document must inform DoD-affiliated personnel about these risks and that they should seek Command or Component guidance before participating.
* If the research involves DoD-affiliated personnel, the researcher must receive Command or Component approval to execute the research.
* Military and civilian supervisors, officers, and others in the chain of command are prohibited from influencing their subordinates to participate in research.
* Military and civilian supervisors, officers, and others in the chain of command must not be present at any recruitment sessions or during the consent process for DoD-affiliated personnel. Excluded supervisors or those in the chain of command may participate in separate recruitment sessions, if applicable.
* Service members and all Reserve Component and National Guard members in federal duty status are considered for purposes of DoDI 3216.02, 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, then the IRB must carefully consider the recruitment process and the necessity of including such member as a human participant.
* In order to approve research involving DoD-affiliated personnel as human participants, the IRB or Component HRPO must determine whether the following requirements have been satisfied:
	+ The consent documentation must include, if applicable, potential risks for the revocation of clearance, credentials, or other privileged access or duty.
	+ For research involving recruitment of DoD-affiliated personnel in greater than minimal risk research, and when recruitment occurs in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:
		- Must not have a conflict of interest with the research or be a part of the research team.
		- Must be present during recruitment, monitoring that the recruitment and informed consent explains 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.
		- Should be available to address DoD-affiliated personnel’s concerns about participation.
* Compensation, including non-monetary compensation, to DoD-affiliated personnel for participation in research while on duty is prohibited other than compensation for blood draws (maximum of $50 per blood draw) in accordance with [24 U.S.C. 30](https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title24-section30)&num=0&edition=prelim). Personnel may be compensated for participation in research when not on duty (e.g., off-hours) in reasonable amounts consistent with local standards and the nature of the research. Plans to compensate participants must be approved by the IRB.
* DoD organizations must demonstrate to the senior designated official that the IRB has fulfilled its duties in accordance with DHHS Subpart D, 45 CFR 46.407 and 21 CFR 50.54

Investigators who intend to recruit DoD-affiliated personnel are advised to seek collaboration with a military investigator familiar with DoD and service-specific requirements. A letter of support from Commanders of military facilities or units in which recruitment will occur or the study will be conducted may be required by the Component HRPO and the IRB. Some military sites may also require that personnel seek written permission from their supervisor prior to participation in research.

When the research includes surveys of DoD personnel, investigators are responsible for ensuring that the survey(s) are submitted to and approved by the DoD Information Management Control Officer (IMCO) prior to implementation but after the research is approved by the IRB. When a survey crosses DoD components, investigators are responsible for ensuring that any additional DoD-required reviews and approvals take place before implementing the survey.

#### 4.0 Component-Level Administrative Review (e.g., Army, Navy, Air Force):

Certain categories of non-exempt human participant research require Component-level administrative review (CLAR) and approval in addition to IRB and the relevant Component’s Human Research Protection Official (CHRPO) approval. These categories include:

* Research that will be conducted in a foreign country, unless the research will be conducted by a DoD overseas institution, or the research only involves DoD-affiliated personnel who are U.S. citizens.
* Research involving a human being as an experimental participant that requires a waiver of informed consent under [10 U.S.C. 980(b)](https://www.govinfo.gov/content/pkg/USCODE-2011-title10/html/USCODE-2011-title10-subtitleA-partII-chap49-sec980.htm).
* The research involves any fetal research participant to [42 U.S.C. 289g-289g-2](https://uscode.house.gov/view.xhtml;jsessionid=B98FC273C93EF5100B62BAEDDA2693DB?req=granuleid%3AUSC-prelim-title42-chapter6A-subchapter3-partH&saved=%7CKHRpdGxlOjQyIHNlY3Rpb246Mjg5Zy0xIGVkaXRpb246cHJlbGltKQ%3D%3D%7C%7C%7C0%7Cfalse%7Cprelim&edition=prelim).
* The research involves the collection of Large Scale Genomic Data (LSGD) from DoD-affiliated personnel. Such research must also undergo DoD Component security review before the research can begin.
* Classified research.
* Research that requires approval by the DoD Office for Human Research Protections (DOHRP).

CLAR also includes review of IRB reliance agreements, when applicable. Principal investigators are advised to check with their sponsoring Component program manager about any additional requirements.

### 5.0 International Research

When conducting human subjects research outside of the United States, the research must be conducted in accordance with U.S. federal and DoD regulatory requirements and the host nation’s laws, as applicable. Host nation laws concerning human subjects research are not typically applicable to DoD-conducted research that only involves DoD-affiliated personnel as research subjects (unless also a citizen of that host nation). DoD Components will consult legal counsel to assess applicability of host nation laws for human participant research. Where differences in applicable standards exist, the standard that is most protective of human subjects will be applied.

The key investigator must 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 participant research that is to be conducted or supported in their area of responsibility before the research may proceed. This does not apply to research performed within the U.S. or at DoD institutions overseas.

Investigators are responsible for ensuring that all DoD-required reviews and approvals take place before the research commences. Investigators must include the appropriate DoD component approval documentation in the IRB submission.

See IRB Policy 6-4 International Research for more information.

# 6.0 Single IRB Mandate:

Effective 20 January 2020, any institution located in the U.S. that is engaged in multi-site cooperative human participants research must rely upon approval by a single IRB for that portion of the research that is conducted in the U.S. unless the relevant DoD Component Office of Human Research Protections (COHRP) determines and documents that use of a single IRB is not appropriate for the particular context of the proposed research. Studies already in progress before January 20, 2020 are not required to transition to a single IRB.

When any institution relies upon another institution’s IRB for DoD-covered research, there must be a written agreement defining the responsibilities and authorities of each institution in complying with the terms of each institution’s Federal Assurance and [DoDD 3216.02](https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf). When appropriate, the lead institution or reviewing IRB may take responsibility for required DoD reporting.

When a DoD institution is engaged in a DoD-covered research study and is relying upon the WSU IRB, each of the following conditions must be met:

* Each institution engaged in non-exempt human participants research must have a current FWA.
* The WSU IRB must be registered in accordance with 45 CFR 46 Subpart E.
* The DoD institution must review the protocol to ensure that all applicable local and DoD requirements are addressed.
* The DoD institution and WSU have a written reliance agreement defining the responsibilities and authorities of each institution in complying with all legal requirements, including that the IRB will apply the DoD requirements outlined in DoDI 3216.02, including the institutional responsibilities outlined in Section 3.6(b).

The primary awardee (lead institution) of a DoD-conducted or supported research proposal that includes a multi-site cooperative effort is responsible for developing a plan for coordinating all collaborating sites’ reliance on a single IRB for DoD-supported multi-site cooperative research.

See IRB Policy 4-17 External IRB & Reliance Agreements for Multi-Site Research for more information.

# 7.0 IRB Procedures:

# Researchers have the following responsibilities for research involving DoD:

# 7.1 Planning: DoD-related research typically requires additional compliance activities, documentation, and participant protections. Researchers should anticipate and plan for these requirements, which may require significant coordination of timing and activities among offices and institutions.

# 7.2 Budgeting: Meeting DoD requirements may increase the costs of conducting the research. DoD has provided the following guidance: “Most costs associated with Human Research Protections are expected to be included in an Institution’s indirect overhead rates. However, if an Institution has identified a specific cost directly associated with performance of a particular effort and thinks the cost should be direct [sic] charted to an award, they should approach the awarding agency Contracting Officer for further consideration. The awarding agency Contracting Officer would normally make a determination as to whether this type of cost is reasonable as a direct cost to their award.”

**7.3 DoD Funding:** Researchers are not allowed to expend DoD funds for human participants research until all of the following requirements have been met:

* The IRB has reviewed and approved the research (or granted a Concurrence of Exemption).
* WSU has furnished the Human Research Protection Program at the DoD component that is funding the research with all of the following:
	+ A copy of the WSU DoD Addendum to its Federal-wide Assurance
	+ Documentation of the IRB approval
	+ If the research qualifies for exemption status, documentation of the exemption, including citation of the exemption category and a rationale statement.
* The WSU SPA office has received notice from the Contracting officer at the DoD component that the DoD Human Research Protection Program has reviewed the research protocol and accepted the IRB approval or exemption determination for compliance with the DoD component policies.

**7.1 Independent scientific review prior to IRB review**:

The **Navy** and the **Army** require independent scientific review and approval **prior to IRB review** of new applications and substantive modifications. This requirement does not apply to research involving other components of the DoD.

* A scientific review conducted by a funding agency or by an established internal review mechanism in the researcher’s school or department will satisfy this requirement. In the absence of such a review, an *ad hoc* scientific review may be provided by the researcher’s chair or dean. It may also be requested of the IRB as a step separate from the IRB review.
* Researchers may wish to look at the Naval Medical Center scientific review template and to the Army’s description of scientific review criteria in its Human Research Protections Office Policies and Procedures. These are essentially the same as the scientific review conducted by any federal funding agency. An internal or *ad hoc* review should cover the same topics, including:
	+ ***Significance*** *–* Does the research address a problem of scientific and/or practical importance? If the aims of the research are achieved, how will scientific knowledge be advanced? What effect will the research have upon the concepts or methods that drive this field of research? Will there potentially be important practical benefits to military and/or civilian communities? Is the research question articulated with clarity and precision? Does the background section describe why the research question is important? Is the literature review comprehensive and complete?
	+ ***Approach*** – Are the conceptual framework, design, methods and analyses adequately developed, feasible, well-integrated, and appropriate to the aims of the study? Are the controls adequate? Does the researcher acknowledge potential problem areas and consider alternative tactics? Is the proposed sample size and statistical analysis valid?
	+ ***Researcher*** – Is the researcher appropriately trained to conduct the research? Is the proposed work appropriate to the experience level of researcher associates?
	+ ***Environment*** – Does the scientific environment in which the study will be done contribute to the probability of success? Does the proposed study take advantage of unique features of the scientific environment or employ useful collaborate arrangements? Are the facilities available and appropriate?

**7.5 Documentation of the scientific review**:

The IRB must be provided with written documentation of the scientific review that summarizes the scientific issues raised and addressed during the review, together with a statement that names and describes the reviewers. Appropriate documentation might include a copy of a review summary from a federal agency, or a memo from the researcher’s department chair.

**7.6 Education and training requirements:**

The DoD education and training requirements may **exceed** requirements of WSU. Initial education and training is described by the DoD as follows: “all personnel involved in reviewing, approving, supporting, conducting, managing, or overseeing research involving human participants must complete initial and ongoing research ethics and human participants protections training appropriate to each individual’s level of involvement, duties, and responsibilities.” [Secretary of Navy, SecNav Instruction 3900.39D]. (Note: WSU mandated online CITI training must also be completed.)

Researchers and appropriate research staff must complete the U.S Department of Defense Requirements for Human Subject Research CITI training module.

**7.7 Documentation responsibilities:**

Researchers are required by DoD policy to maintain an extensive number of research-related and compliance-related documents in their files. Researchers should contact the specific DoD component funding the research for specifics on these requirements.

Records maintained that document compliance or non-compliance with DoD requirements shall be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD component.

See IRB Policy 4-15 Document Retention for Research Protocols for more information.

**7.8 Additional DoD Review Required Prior to Initiation of Study:**

After the IRB completes its review and issues approval, the PI must submit documentation of IRB approval to the DoD Component sponsoring or supporting the study. This approval must include the risk level and expiration date of the research.

The DoD may also request additional documentation to verify compliance with federal and DoD policies, including minutes related to the research.

The PI may not initiate the study until the human research protection officer within the sponsoring DoD component reviews and approves the IRB approval and other submitted documentation.

**8.0 Post-IRB Responsibilities:**

* Continuing education – as described above, the DoD requires annual continuing education related to human participants for the researchers and appropriate research staff.
* Research results – DoD requires that the researcher provide the IRB with copies of publications, presentations, and reports resulting from the research.
* The DoD may require research records be submitted to the DoD for archiving.
* Modifications to the research – DoD requires that all substantive amendments to approved DoD research (e.g., new procedures, a new participant population, a new aim) involving human participants receive scientific review **prior** to IRB review. This can be done by the Department Chair or his/her designee.
	+ When preparing an Amendment Form to the IRB for review, the researcher is responsible for reviewing the Protocol, Protocol Summary Form, consents, and other applicable documents to ensure that they accurately reflect the research.
	+ If the research was not previously DoD-related, but the Amendment will make it DoD-related, the researcher must submit all DoD-required information along with the Amendment Form, per IRB Amendment Form directions.
* Reporting obligations – The researcher is responsible for notifying DoD and the IRB of any audits, investigations, or inspections of DoD-related research.

### 8.1 Reporting Requirements

WSU investigators must promptly (i.e., no longer than within 30 days or as defined by the DoD Component) notify the Component Office of Human Research Protections (COHRP) of the following:

* IRB-approved changes to research that involve:
	+ changes to key investigators or institutions.
	+ decreased benefit or increased risk to participants in greater than minimal risk research.
	+ addition of vulnerable populations.
	+ addition of DoD-affiliated personnel as participants.
* Audit reports of DoD-conducted or DoD supported human participant research when conducted by another federal or state agency, official governing body of a Native American or Alaskan native tribe, other official entity, or foreign government.

**Note:** Investigators should be aware that the DoD Component HRPO may require HRPO approval of IRB-approved changes to research before the changes are implemented.

* Transfer of IRB oversight to a different IRB.
* 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 participants research is being audited or is under for cause investigation, and the subsequent report.
	+ A follow-up to the initial notification report must be submitted to the IRB with the report of the audit findings.
* Any unanticipated problems involving risks to participants or others, suspension or termination of IRB approval, or any serious or continuing noncompliance pertaining to DoD-supported research, and the actions taken as a result. Note: Substantiated allegations related to classified research must be reported immediately. See IRB Policy 13-1 Unanticipated Problems and Other Reportable Events for more information.
* The results of the IRB’s continuing review, when continuing review is required.
* Change in status when a previously enrolled human participant becomes pregnant, or when the researcher learns that a previously enrolled human participant is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with Subpart B of 45 CFR 46.
* Change in status when a previously enrolled human participant becomes a prisoner, and the protocol was not reviewed and approved by the IRB in accordance with Subpart C of 32 CFR 219.
* A DoD-supported study’s closure.

### 8.2 Addressing and Reporting Allegations of Noncompliance

The WSU IRB must respond to allegations of noncompliance with [DoDI 3216.02](https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf) or other requirements and conduct an investigation in accordance with the agreement in place with relevant DoD component. Allegations of noncompliance must be promptly and properly investigated. Substantiated serious and/or continuing non-compliance findings must be promptly reported to the DoD Component via the Component HRPO. **If the research is classified, substantiated allegations must be reported immediately**.

The Institutional Official is responsible for reporting non-compliance and reviewing the final non-compliance report.

See IRB Policy 15-1 Identifying, Defining and Managing Non-Compliance in Human Research for more information.

#### 8.3 Requirements for Large Scale Genomic Data (LSGD) Research on DoD-Affiliate Personnel

DoD-conducted or supported research involving LSGD collected on DoD-affiliated personnel, or for which research the DoD provides assistance, is subject to the following additional requirements:

* 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.
* All research involving LSGD collected from DoD-affiliated personnel must be covered by a Certificate of Confidentiality (CoC). Exceptions to the CoC must be listed in the informed consent form.
* 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.

# 9.0 References

# 45 CFR 46Title 45 Code of Federal Regulations, part 46 (45 CFR 46) is the primary set of Federal regulations regarding the protection of human subjects in research and is often referred to as the Common Rule. It defines the laws, criteria for exemption, as well as definition and formulation of Institutional Review Boards (IRB’s). Some Government agencies (e.g., DoD, FDA, etc.) have established their own implementation of this code that supersedes portions or all of 45 CFR 46. See <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

# 32 CFR 219 This is the Department of Defense (DoD) implementation of 45 CFR 46, Subpart A. Subparts B, C, and D of 45 CFR 46 still apply to DoD supported research. It differs from 45 CFR 46 in the criteria for exemptions.

# DoD Directive 3216.02 This document defines additional requirements for human subject research supported by the Department of Defense. See <http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>

# 10 USC 980 Title 10, United States Code, Subtitle A, Part II, Chapter 49, Section 980 (10 USC 980) addresses the limitations on use of humans as experimental subjects. It basically states that funds cannot be deployed prior to obtaining informed consent. See <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+10USC980>

# 21 CFR 50.24 This document addresses the Food & Drug Administrations, Department of Health & Human Services, Part 50, Subpart B, Informed Consent of Human Subjects. See <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.24>

# 9.1 DoD Acronyms:

# CLAR- Component-Level Administrative Review

# COHRP- Component Office of Human Research Protections

# DoDI- DoD Instruction

# DOHRP- DoD Office for Human Research Protections

# HRPO- Human Research Protection Official

# HRPP- Human Research Protection Program

# HSR- Human Participant Research

# LSGD- Large Scale Genomic Data