

<b>Title:</b>	Research with the Department of Defense (DoD)
<b>Last Approval Date:</b>	2/9/19
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<b>Policy and SOP:</b>	4

#### **4.1 Executive Summary**

The NC State IRB office agrees to comply with the Department of Defense (DoD) regulations including, but not limited to, DoDI 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research.

This document outlines expectations for all research completed by NC State that is associated with the DoD, including items required in the IRB application and additional requirements once NC State IRB approval is granted.

#### **4.2. Policy**

All research completed by NC State researchers that is funded by the DoD, or uses any DoD resources or people adhere to additional requirements as stated by the DoD.

#### **4.3. Standard Operating Procedure (SOP)**

When performing research with human subjects that is funded by the DoD or uses any DoD resources or people (including ROTC), your research is considered supported by DoD and you need to adhere to the following requirements from the DoD regarding research with human subjects.

#### **4.3.a. Additional Procedures to be Included in the NC State IRB protocol and required Text for Research Documents:**

1. In the IRB Application/Protocol
  - a. Include the letters "DoD" at the beginning of the IRB protocol title
  - b. List "DoD" under "Source of Funding" if it is funded by the DoD and link the IRB record to the sponsored project record for the project
  - c. All researchers conducting human subjects research affiliated with the DoD must undergo training regarding Human Subjects Research. Proof of education must be submitted with the IRB application.
  - d. You must include a "Scientific Merit review" when submitting to the IRB (see section 4.3.e).
  - e. Information regarding compliance with international laws must be stated clearly in the IRB application.
  - f. For more than minimal risk research, use of research monitor is required. This monitor must be independent of the research team and possess appropriate expertise to identify risks of the research.
2. General Procedural Information
  - a. You must maintain research records for at a minimum of three years after the completion of the study.
  - b. All findings of serious or continuing noncompliance shall be reported to the appropriate DoD officials in a timely manner.
3. Required Text for Study Documents
  - a. Consent forms must list the DoD as a source of funding for the research.
  - b. Consent forms must state that representatives of the DoD are authorized to view research records.

#### **4.3.b. DoD Personnel as Research Participants**

This applies to all research that includes DoD personnel as study participants, regardless of funding.

1. Role of Supervisors and Commanding Officers
  - a. Supervisors or commanding officers cannot direct or otherwise influence the decision of their subordinates to participate in the research.
  - b. Supervisors or commanding officers cannot be present during the recruitment sessions or consent processes.
  - c. When applicable, supervisors shall be offered the opportunity to participate in research.
2. Participating in Research while On/Off Duty
  - a. Service members shall follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty.
  - b. Service members shall follow their Component and command's policies for approving off-duty employment or activities.

3. For Greater than Minimal Risk Research
  - a. For research that is greater than minimal risk, involves service members, and involves group level recruitment, an ombudsman who is not associated with the research must be assigned to monitor the voluntary nature of participation.
  - b. For research involving Service members as human subjects that has been determined to be greater than minimal risk and when recruitment occurs in a group setting, the IRB shall appoint an ombudsman.
    - i. The ombudsman shall not be associated in any way to the research and shall be present during the recruitment in order to monitor that the voluntary involvement or recruitment of the Service members is clearly and adequately stressed and that the information provided about the research is clear, adequate, and accurate.
    - ii. The ombudsman may also be the research monitor

**4.3.c. After any IRB determination from the NCSU IRB, your project will need to undergo a secondary "Human Research Protection Officer" (HRPO) review by DoD.**

1. You will need to undergo HRPO review regardless of level of review assigned by the NC State IRB (this includes determinations of Exemption and Not Human Subjects Research).
2. You will need to undergo this HRPO review if DoD employees are included as research participants or if the project is supported in another way by the DoD.
3. You are responsible for coordinating this review.
4. Once approved by the NC State IRB, all amendment approvals and continuation of approval notifications must be submitted for HRPO review.
5. An official approval letter generated by the NC State IRB office will be uploaded to the electronic IRB system. This letter will need to be submitted with your HRPO review.

**4.3.d. After any IRB approval you will need to provide the following information to the HRPO officer managing your study:**

1. This applies to initial reviews, amendment requests, and continuing approval requests.
2. A copy of the approval letter you received from the eIRB system, uploaded by the IRB staff.
3. A copy of your approved IRB protocol.
4. A copy of all approved study materials including, but not limited to recruitment materials, consent forms, and any data collection instruments.
5. Copies of any contracts or proposals related to the DoD funds.
6. Copies of education certification (via the CITI training website, this should also be included in your IRB application)

**4.3.e. Scientific Merit Review**

1. If your research receives expedited or full board review, your project must undergo a "Scientific Merit Review" in addition to IRB review.
  - a. Scientific Merit review is an independent review and approval that assesses the scientific merit of a study.
  - b. A Scientific Merit Review needs to be conducted by a funding agency, an established review mechanism in the researcher's department/school, or a Dean/Department Head with expertise in the area.
2. If you are working with the Army or Navy, this review must be completed before IRB approval is granted. For all other DoD affiliates, it must be submitted with your HRPO review (after NCSU IRB approval and before HRPO review).
3. If you are affiliated with the Laboratory for Analytical Sciences (LAS), this Scientific Merit Review can be facilitated by LAS staff.
4. LAS and projects funded as a DoD Science of Security also will require you to complete a closure report to the relevant DoD point of contact (POC) and to the NCSU IRB Office.
  - a. You will need to submit the closure report to the NCSU IRB office as an Amendment Request. Once this is submitted, the IRB will note it in your IRB protocol.
  - b. You are responsible for communicating this report to the relevant LAS or DoD Science of Security Label POC.

5. The IRB office will not complete or facilitate the scientific merit review for you. You must include this review with your IRB application, and if you do not, you must state why.

## **Appendix A**

### **[Department of Defense 3216.02](#), Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research.**

**Department of Defense (DoD) entities include (but may not be limited to) these groups:**

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

## Appendix B Definitions

**DoD-conducted research involving human subjects:** Research involving human subjects that is performed by DoD personnel. Intramural research is one type of DoD-conducted research involving human subjects. See “engaged in research involving human subjects.”

- **DoD personnel** DoD civilian employees and members of the military services.
- **DoD civilian employee** An individual meeting the definition of “employee” consistent with section 2105 of Reference (m). It includes employees of DoD Non-Appropriated Fund Instrumentalities; DoD civilian employees filling full-time, part-time, intermittent, or on-call positions; and individuals serving under personal services contracts consistent with section 2.101 of Reference (n). It excludes employees of contractors (other than personal services contractors) and foreign nationals of host countries.
- **Service members** Individuals appointed, enlisted, or inducted for military service under the authority of the Department of Defense. The Military Services are the Army, the Navy, the Air Force, the Marine Corps, the Coast Guard, and the Reserve Components, which includes the Army and the Air National Guards of the United States. Members of the Reserve Components are included when in a duty status.

**DoD-supported research involving human subjects:** Research involving human subjects for which the Department of Defense is providing at least some of the resources (see “research involving human subjects”).

- Resources may include but are not limited to funding, facilities, equipment, personnel (investigators or other personnel performing tasks identified in the research protocol), access to or information about DoD personnel for recruitment, or identifiable data or specimens from living individuals.
- It includes both DoD-conducted research involving human subjects (intramural research) and research conducted by a non-DoD institution.

**HRPO:** An individual who is delegated the responsibilities as defined in paragraph (a)(2) of section 252.235-7004 of Reference (n). There may be more than one HRPO in a DoD Component. Some DoD Components may use a different title for the person(s) with the defined responsibilities.

**Intramural Research:** Research that is conducted by an entity that is part of the Department of Defense.

**Ombudsman:** A person who acts as an impartial and objective advocate for human subjects participating in research.

**Research Monitor:** Individuals with expertise consonant with the nature of risk(s) identified within the research protocol, whose role is to protect the safety and well-being of human subjects.

- There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board.
- The duties of the research monitor shall be determined on the basis of specific risks or concerns about the research. The research monitor may perform oversight functions (e.g., observe recruitment, enrollment procedures, and the consent process for individuals, groups or units; oversee study interventions and interactions; review monitoring plans and UPIRTSO reports; and oversee data matching, data collection, and analysis) and report their observations and findings to the IRB or a designated official.
- The research monitor may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research. The research monitor shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report. Research monitors shall have the responsibility to promptly report their observations and findings to the IRB or other designated official.
- The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities. The IRB or HRPP official shall communicate with research monitors to confirm their duties, authorities, and responsibilities.
- The research monitors shall have expertise consonant with the nature of risk(s) identified within the research protocol, and they shall be independent of the team conducting the research involving human subjects.

## **Appendix C**

### **General Information From DoD – I**

#### **DoD Component Review, Approval, and Oversight**

- When the contract or other agreement may include research involving human subjects and if the non-DoD institution determines either the activity is not research involving human subjects or is exempt research involving human subjects, the HRPO must concur with the performing institution's determination before activity can begin.
- If the non-DoD institution determines the activity is non-exempt research involving human subjects, the HRPO must perform an administrative review of the research before the activities that involve human subjects can begin (e.g., human subject recruitment and data collection).

#### **Human Subjects and Medical Expenses if Injured**

- **DoD-Supported Research Involving Human Subjects.**

All non-exempt research involving human subjects shall, at a minimum, meet the requirement of section 219.116(a)(6) of Reference (c). The Common Rule does not require payment or reimbursement of medical expenses, provision of medical care, or compensation for research-related injuries.

- **DoD-Conducted Research Involving Human Subjects.**

The DoD Components shall establish procedures to protect human subjects from medical expenses (not otherwise provided or reimbursed) that are the direct result of participation in DoD-conducted non-exempt research involving human subjects that involves more than minimal risk. Such procedures may consist of utilizing the Secretarial Designee program as described by section 108.4(i) of Reference (c) during the period of the human subject's involvement in the research, which may be extended further upon the approval of the USD(P&R). DoD Components may supplement this Secretarial Designee procedure with additional procedures consistent with applicable authority. This requirement does not apply when the Department of Defense is supporting the research but is not engaged in the non-exempt research involving human subjects (i.e., when the non-exempt research involving human subjects is performed solely by non-DoD institutions).

- **DoD Collaborative Research Involving Human Subjects**

When collaborating with a non-DoD institution, the DoD Components shall establish procedures comparable to those required by paragraph 10.b. of this section to protect human subjects from medical expenses (not otherwise provided or reimbursed) that are the direct result of participation in non-exempt research involving human subjects and that are a direct result of research activities performed by DoD personnel. This does not apply to expenses resulting from the injury due to actions performed by the non-DoD institution(s).

When DoD personnel are conducting the research involving human subjects at the collaborating institution and the Department of Defense does not have the primary involvement, the DoD Components are not required to have procedures to protect human subjects from medical expenses. For this purpose the determination of primary involvement shall be based on consideration of the type and portion of the DoD involvement in the collaborative research (e.g., research staff, human subjects, facilities, equipment, IRB, and all other assets).

When the collaboration is such that it is difficult to separate DoD involvement from that of the non-DoD institution, the Head of the OSD or DoD Component may waive this requirement to have procedures to protect human subjects from medical expenses. This waiver authority may be delegated, as described in the Component's HRPP management plan, but not at or below the position of the institution's DoD IO.