4.1 Executive Summary
The NC State IRB office complies with the Department of Defense regulations, 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 Department of Defense (DoD) or uses any DoD resources or people, must 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 Department of Defense (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. Required Text in Documents and Additional Procedures to be Included in the NC State IRB protocol:

1. Consent forms must list the DoD as a source of funding for the research
2. Consent forms must state that representatives of the DoD are authorized to view research records
3. 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.
4. Include the letters “DoD” at the beginning of the IRB protocol title
5. List “DoD” under “Source of Funding” if it is funded by the DoD
   a. Link the eIRB record to the sponsored project record for the project
6. You must include a “Scientific Merit review” upon submission to the IRB (see section 4.3.e)
7. Information regarding compliance with international laws must be stated clearly in the IRB application.

4.3.b. DoD Personnel as Research Participants

1. This applies to all research that includes DoD personnel as study participants, regardless of funding.
2. Supervisors or commanding officers cannot influence the decision of their subordinates to participate in the research
3. Supervisors or commanding officers cannot be present during the recruitment sessions or consent processes.
4. 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 much be assigned to monitor the voluntary nature of participation.
5. When applicable, supervisors shall be offered the opportunity to participate in research.
4.3.c. After any IRB approval from the NCSU IRB, your project will need to undergo a secondary “Human Research Protection Officer” (HRPO) review.

1. You are responsible for coordinating this review.
2. You will need to undergo HRPO review regardless of level of review assigned by the NC State IRB.
3. 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.
4. Once approved by the NC State IRB, all amendment approvals and continuation of approval notifications must be submitted for 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.
3. A copy of your approved IRB protocol.
4. A copy of all approved study materials.
5. Copies of any contracts or proposals related to the DoD funds.
6. Copies of education certification (via the CITI training website).

4.3.e. Scientific Merit Review

1. If your research receives expedited or full board review, your project will 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 will also require you to complete a closure report to them and to the NCSU IRB Office.
   a. You will need to submit this report to the NCSU IRB office as an Amendment Request. Once this is submitted, the IRB will note it in your eIRB protocol.
   b. You are responsible for communicating this report to LAS.
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