

**Department of Navy
Human Research Protection Program
(DON HRPP)**

[Command requesting the Assurance]

**Policy and Procedures for Initiating, Monitoring & Overseeing, and Completing Research
with Human Subjects**

Background

As required by its Assurance for the Protection of Human Research Subjects, **[Command requesting the Assurance]** is responsible for the performance of all research covered by its Assurance, including full responsibility for compliance with applicable federal regulations and laws, Department of Defense directives, Department of the Navy instructions and guidance, and state and local laws.

Policy

[Command requesting the Assurance] relies on the Institutional Review Board (IRB) at **[Commands listed in its DoD N Assurance]** for review and recommendation about research protocols involving human subjects. **[Command requesting the Assurance]** Commanding Officer must concur in writing with the IRB recommendation for approval before supporting, funding, or starting the research.

[Command requesting the Assurance] designates **[add the title or position of this individual]** as the Primary Contact for the Command's Human Research Protection Program (HRPP).

In the areas of research misconduct, and allegations of non-compliance with human subject research protections, **[Command requesting the Assurance]** will initiate the inquiry, consult with the reviewing IRB as appropriate, and follow the policies and procedures of those IRBs as a guide.

Procedures

1. Submission of Research Protocols for Review

a. Command HRPP POC coordinates the Command's review, endorsement, and submission of research protocol to the command with the reviewing IRB.

(1) Verifies that investigators have met and documented the initial and continuing education and training requirements by including the documentation in the research protocol submission to the command with the reviewing IRB.

(2) Addresses conflicts of interest for those involved in reviewing, approving, conducting, managing, overseeing, or supporting human subject research.

2. Monitoring and Overseeing the HRPP and Research Protocols

- a. The Institutional Official may suspend or terminate research protocols.
- b. Command HRPP POC maintains communication with the reviewing IRB and monitors and oversees human subject research, as follows:
 - (1) Conducts an administrative overview, at least annually to ensure effectiveness of policies and procedures.
 - (2) Meets with investigators to review research protocol practices and documentation at least once per year, or more frequently depending on the research.
 - (3) Verifies that investigators have reported promptly any amendments to the research to the command with the reviewing IRB and have not initiated them without IRB approval, except when necessary to eliminate apparent immediate hazards to subjects or others.
 - (4) Addresses conflicts of interest that may occur after the initial IRB-approval for those involved in reviewing, approving, conducting, managing, overseeing, or supporting human subject research.
 - (5) Verifies that investigators have provided a copy of the IRB-approved informed consent document with all signatures to each subject at the time of consent, unless the IRB specifically has waived this requirement.
 - (6) Reports the results of the monitoring to the Institutional Official and the reviewing IRB.
 - (7) Reports to the Institutional Official and the reviewing IRB, any unanticipated problems involving risks to subjects or others; serious adverse events; and any serious or continuing noncompliance by investigators. The Institutional Official is responsible for reporting such problems, events, and non-compliance to the DON HRPP, sponsors, and applicable regulatory agencies, as appropriate.
 - (8) Verifies that investigators maintain, at a minimum, the following research protocol documents:
 - a. Research protocol, including all supporting documents (data abstraction forms, recruitment materials, advertisements, etc.) approved by the IRB.
 - b. Informed Consent Document, if applicable, approved by the IRB.
 - c. Command approval document, including IRB recommendation, to start the research.
 - d. Continuing review reports, amendments, other reports (unanticipated problems, serious adverse events, protocol deviations, subject complaints etc.), and the final report.

- e. Command documents approving continuing review and amendments to previously-approved research.
- f. All correspondence between investigators and the IRB.

(9) Verifies that research documents are secured to maintain privacy and confidentiality as described in the research protocol.

(10) Ensures that publications and presentations resulting from research with human subjects are properly cleared through the **[Command requesting the Assurance]**, the reviewing IRB, if applicable, and others as appropriate, using DON HRPP guidelines.

(11) Addresses allegations of non-compliance with the federal regulations, the Assurance, or the Command/IRB-approved research protocol.

(12) Addresses allegations of research misconduct.

(13) Maintains documentation for Command oversight responsibility, including a current Assurance, Agreements and correspondence with the reviewing IRB, and research protocol documents.

(14) Ensures protocols approved by the Institutional Official are forwarded to DON HRPP.

3. Completion of Research

a. Command HRPP POC ensures that:

- (1) Investigators submit final report (the last continuing review) upon completion or closure of the research.
- (2) Upon change of duty, investigators transfer on-going research protocols to other investigators or submit a final report.
- (3) Command maintains required documents.

Verified by:

Signature:

Date:

Name:

Title: