



DEPARTMENT OF THE NAVY
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3900
MRA

JAN 24 2014

From: Deputy Commandant, Manpower and Reserve Affairs
To: Distribution List

Subj: M&RA HUMAN RESEARCH PROTECTION PROGRAM (HRPP) POLICY AND PROCEDURES

Ref: (a) MCO 3900.18

Encl: (1) M&RA Human Research Protection Program Policies and Procedures

1. Per the reference, M&RA has established its own Human Research Protection Program. I have appointed the Assistant Deputy Commandant, M&RA, Mrs. Sheryl Murray, as the Institutional Official.

2. The Marine Corps recently established its own Institutional Review Board. In light of that change, M&RA has updated our Policy and Procedures for Initiating, Monitoring & Overseeing, and Completing Research with Human Subjects [encl (1)].

3. M&RA has also established an informational website for the HRPP that can be found at:
[https://www.manpower.usmc.mil/portal/page/portal/M_RA_HOME/MP/z%20Human%20Research%20Protection%20Program%20\(HRPP\)](https://www.manpower.usmc.mil/portal/page/portal/M_RA_HOME/MP/z%20Human%20Research%20Protection%20Program%20(HRPP))

4. Please contact MPP-50 at 703-784-9367 if you have any questions.


R. E. MILSTEAD JR

Copy to:
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USMC IRB Chair

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

Manpower & Reserve Affairs Department Headquarters USMC

**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, the Assistant Deputy Commandant (ADC), **Manpower & Reserve Affairs (M&RA) Department, Headquarters USMC** 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:

ADC, Manpower & Reserve Affairs relies on the Marine Corps Institutional Review Board (IRB) listed in its Department of Navy Assurance for review and recommendation about research protocols involving human subjects. ADC, M&RA follows the USMC IRB HRPP Policy and Procedures for proper submission of human-subject research protocol. ADC, M&RA must concur with the IRB recommendation for approval before supporting, funding, or starting the research.

ADC, M&RA designates Ms. Cheryl L. Fitzgerald, Section Head, MPP-50 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, ADC, M&RA 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 ADC, M&RA 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 ADC, M&RA and the reviewing IRB.
- (7) Reports to the ADC, M&RA 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 ADC, M&RA 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) Addresses allegations of non-compliance with the federal regulations, the Assurance, or the Command/IRB-approved research protocol.
- (11) Addresses allegations of research misconduct.


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

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: M&RA Institutional Official

Signature:  Date: 24 Jan 2014

Name: Sheryl E. Murray

Title: Assistant Deputy Commandant, Manpower & Reserve Affairs