



UNITED STATES MARINE CORPS

MARINE CORPS SYSTEMS COMMAND
2200 LESTER STREET
QUANTICO, VIRGINIA 22134-5050

MARCORSYSCOMO 3900.1

G-3

22 Sep 21

MARINE CORPS SYSTEMS COMMAND ORDER 3900.1

From: Commander

To: Distribution List

Subj: PROCEDURE FOR HUMAN RESEARCH PROTECTION PROGRAM PROTOCOL
SUBMISSION AND EXEMPTION DETERMINATION PROCESS

Ref: (a) MARCORSYSCOM DoD N-40075 Department of Defense - Navy
Assurance for the Protection of Human Research
Subjects

Encl: (1) MARCORSYSCOM Roles and Responsibilities for Commands
without Their Own Institutional Review Board

1. Situation. Per reference (a), the Institutional Official (IO) is authorized to review and approve human subjects research studies conducted under the jurisdiction of Marine Corps Systems Command (MARCORSYSCOM). Under the terms of the Institutional Review Board (IRB) agreement, the USMC IRB will provide review and oversight support. However, MARCORSYSCOM retains full responsibility for the conduct of the research. The MARCORSYSCOM Human Research Protection Official (HRPO) shall be used for passing and tracking of Human Research Protection Program (HRPP) documents between the investigators, USMC IRB, and MARCORSYSCOM IO.

2. Cancellation. Not applicable.

3. Mission. To standardize and streamline the process of Human Subjects Research (HSR) determinations and signature attainment for HRPP documents from the USMC IRB and MARCORSYSCOM IO.

4. Execution

a. Commander's Intent and Concept of Operations

(1) Commander's Intent. The MARCORSYSCOM HRPO is the focal point for all HRPP documents requiring review by the USMC IRB and the research approval signature by the MARCORSYSCOM IO.

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distribution is unlimited.

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The HRPO also conducts the review of documentation submitted by non-DoD institutions in accordance with the terms of Defense Federal Acquisition Supplement (DFARS) 252.235-7004 or comparable language for grants, assistance agreements, Cooperative Research and Development Agreements and other agreements.

(2) Concept of Operations. Program Managers (PMs) shall utilize enclosure (1) for Human Subjects Research (HSR) protocol submissions and determination requests through the MARCORSYSCOM HRPO. The MARCORSYSCOM HRPP follows the USMC IRB HRPP Policy and Procedures. The MARCORSYSCOM IO must concur with the IRB recommendation for HSR approval prior to the support, funding or start of the research. HRPP information can be accessed online via the MCSC Centrally-Managed Survey Process:
https://mcscviper.usmc.mil/sites/kc/MCSC_Surveys/SitePages/MCSC%20Surveys.aspx.

5. Administration and Logistics. Distribution Statement A directives issued by Commander, MARCORSYSCOM are published electronically and can be accessed online via the Command Library at:
<https://mcscviper.usmc.mil/sites/kc/AMHS/default.aspx>.

6. Command and Signal

a. Command. This Order is applicable to all of MARCORSYSCOM and the supported Program Executive Officers.

b. Signal. This Order is effective the date signed and remains in effect until cancelled.

W. S. WILLIFORD
Executive Director

DISTRIBUTION: A

Command without IRB

Marine Corps Systems Command
 Human Research Protection Program
 Protocol Submission Process and Chain of Communication
 For Commands without Their Own IRB

ROLE	RESPONSIBILITIES
<p align="center">Principal Investigator (PI)</p>	<ul style="list-style-type: none"> ▪ Completes education requirements & provides documentation to MARCORSYSCOM HRPP POC ▪ Drafts research protocols including consent documents and other appropriate documents and forms
<p align="center">↓</p> <p align="center">PI's Program Manager or Competency Director</p>	<ul style="list-style-type: none"> ▪ Endorses research protocol for submission
<p align="center">↓</p> <p align="center">MARCORSYSCOM HRPP POC</p>	<ul style="list-style-type: none"> ▪ Coordinates for required scientific review (may establish agreement with another command to do scientific review) ▪ Coordinates review of research protocol within command and among other commands, as appropriate ▪ May coordinate preparation of agreements ▪ MARCORSYSCOM HRPP POC concurs with PI's test protocol submission to Command with reviewing IRB
<p align="center">↓</p> <p align="center">Review by Command with Reviewing IRB</p>	<ul style="list-style-type: none"> • Makes determination of Human Subject Research • Conducts IRB review of human subject research protocol • Notifies MARCORSYSCOM HRPP POC of IRB review results • Prepares Transmittal letter to MARCORSYSCOM IO for approval of IRB recommendation
<p align="center">↓</p> <p align="center">MARCORSYSCOM HRPP POC, Institutional Official (IO)</p>	<ul style="list-style-type: none"> ▪ IRB Chair routes IRB recommendation approval letter to MARCORSYSCOM IO via the MARCORSYSCOM HRPP POC ▪ MARCORSYSCOM HRPP POC coordinates routing to IO for review and approval. Returns approval endorsement to IRB Chair.
<p align="center">↓</p> <p align="center">IRB Chair of Command with Reviewing IRB</p>	<ul style="list-style-type: none"> • Provides the PI with a copy of the IO's approval, copy to the MARCORSYSCOM HRPP POC. • Provides the PI with information on required reviews, process for unanticipated problems, etc. Copy to MARCORSYSCOM HRPP POC.
<p align="center">↓</p> <p align="center">MARCORSYSCOM HRPP POC</p>	<ul style="list-style-type: none"> ▪ Maintains communications between IO, PI and IRB ▪ Conducts oversight and monitoring ▪ Reports to IO and DON HRPP
<p align="center">↓</p> <p align="center">PI</p>	<ul style="list-style-type: none"> ▪ Conducts research according to approved test protocol ▪ Submits, using same process as above for: <ul style="list-style-type: none"> ▪ Continuing reviews ▪ Amendments to test protocol ▪ Unanticipated problems, serious adverse events, protocol deviations, subject complaints ▪ Final report

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

Marine Corps Systems Command

**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, Marine Corps Systems Command 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

1. Marine Corps Systems Command relies on the Institutional Review Board (IRB) at U.S. Marine Corps (USMC) for review and recommendation about research protocols involving human subjects. Marine Corps Systems Command Commanding Officer must concur in writing with the IRB recommendation for approval before supporting, funding, or starting the research.
2. Marine Corps Systems Command designates the Human Research Protection Official (HRPO) as the Primary Contact for the Command's Human Research Protection Program (HRPP).
3. In the areas of research misconduct, and allegations of non-compliance with human subject research protections, Marine Corps Systems Command 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. Command HRPP POC coordinates the Command's review, endorsement, and submission of research protocol to the command with the reviewing IRB.
 - a. 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.
 - b. 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 and 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 Marine Corps Systems Command, 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.

3. Completion of Research. Command HRPP POC ensures that:

a. Investigators submit final report (the last continuing review) upon completion or closure of the research.

b. Upon change of duty, investigators transfer on-going research protocols to other investigators or submit a final report.

c. Command maintains required documents.

Verified by:

Signature
Name: Mr. W. S. Williford
Title: Institutional Official

Date: 22 Sep 21