

## **Human Subjects Research and Research Approval**

Functional Lead: Vice President for Operations and Plans

Division: Institutional Research Analysis and Planning

Responsible Office: Institutional Research Analysis and Planning

1. Purpose. This section contains the policies and procedures related to planning and conducting research involving human participants or subjects. These review processes ensure the protection of the rights and welfare of research subjects in accordance with Federal law and Department of Defense (DoD) regulations.

2. Overview. Human subjects research (HSR) regulations encompass all research that includes interviews, focus groups, observations, surveys, or any methods involving gathering information from or about people. It also includes research seeking access to secondary data sets that may contain private identifiable information or may not be publicly available. All such research conducted or contracted by Marine Corps University (MCU), or research support requested by external researchers from MCU, must be reviewed according to the requirements of the United States Marine Corps (USMC) Human Research Protection Program (HRPP). These reviews typically are conducted by the Marine Corps' Institutional Review Board (IRB) with MCU's IRB Vice Chair coordinating submission. The IRB is part of the HRPP. In this policy, the term IRB is used to facilitate reader understanding.

3. Organization. The specific requirements and procedures vary depending on who is doing the research and whether or not MCU personnel, students, facilities, or resources are being used:

a. Research conducted by MCU faculty, staff, and students: Subsection 1 outlines those procedures relevant to research conducted by MCU faculty, staff, or students.

b. Contracted research activities: Subsection 2 details the requirements for contracted research activities.

c. Research seeking to use MCU personnel or students or other MCU resources: Subsection 3 addresses the approval requirements for any research that recruits MCU employees or students as research subjects, requests access to MCU data, or requests the use of MCU facilities, resources, or equipment for the conduct of research. These policies and procedures also apply to researchers seeking General Officer (GO) endorsement of a research topic that is under MCU oversight.

4. Research and Sponsored Projects Portal. The primary source of up-to-date information on procedures and forms related to HSR is MCU's intranet. Individuals planning research should visit the appropriate pages to get information on applicable review processes, policies, and procedures.

### **Subsection 1: Research Conducted by MCU Faculty, Staff, and Students**

Reference: (a) MCO 3900.18 HRPP

(b) MARADMIN 208/11

(c) SECNAVINST 3900.39

(d) DoDI 3216.02

(e) USMC Human Research Protection Program Policy and Procedures

1. Purpose. This subsection outlines the policies and procedures established to ensure research conducted by MCU's faculty, staff, and students complies with federal law and DoD and Marine Corps policies.

2. Overview

a. The Marine Corps' IRB reviews research to ensure the protection of the rights and welfare of human research subjects in accordance with Federal law and DoD regulations. The Marine Corps' IRB exists to protect Marines and all other participants in Marine Corps research from harm by minimizing risk to subjects, ensuring informed consent, and reviewing adequate protection of private and confidential data. The IRB is authorized to review requests to conduct research involving human subjects and recommend approval or disapproval to the Institutional Official, currently the Executive Deputy of Training and Education Command (TECOM). The IRB also may recommend modifications to the request, with approval suspended pending submission of a modified request. No human subject research in any form (including recruitment, consent, or data collection) can take place without review and approval by the Marine Corps' IRB and its Institutional Officials.

b. All forms, policies, and procedures referenced in this section are available on MCU's Knowledge Management Portal.

3. Policy

a. Scope. MCU complies with all standards and requirements outlined in the references. Accordingly, any research involving identifiable data sets, interviews, focus groups, observation, surveys, or any methods involving gathering information from or about people must go through an applicability review coordinated by the MCU IRB Vice Chair prior to beginning recruitment or data collection. This review also allows the Vice Chair to assess whether the proposed research may be considered part of an existing activity that has already been reviewed by the IRB, such as routine curriculum and program reviews, thereby avoiding unnecessary and duplicative review processes. The procedures below apply to faculty, students, and staff assigned to MCU.

b. Responsibilities

(1) Researchers. The Principal Investigator (PI) for a project has overall responsibility for ensuring research compliance with applicable regulations, directives, and instructions, including the conduct of research, storage of data and records during the project, and long-term storage of research records. These and other requirements are outlined in reference (e). A student may serve as a PI on a research project; however, student research compliance must be closely supervised by faculty advisors/mentors to ensure proper project conduct and closure of the project and transfer of required records to MCU's centralized storage.

(2) Supervisors and Faculty Advisors/Mentors. In accordance with reference (e), when a full protocol is required by the IRB, supervisors or faculty advisors sign an IRB Action Request form in order to certify that the research is deemed scientifically sound and is being managed by their department.

(3) MCU IRB Vice Chair. Currently, MCU's Director of Academic Support Division serves as the MCU IRB Vice Chair to the Marine Corps' IRB and fulfills all Vice Chair requirements outlined at reference (e).

(4) MCU IRB Alternate Vice Chair. The appointed alternate vice chair serves as the alternate MCU member to the Marine Corps' IRB and fulfills all alternate member requirements outlined in reference (e).

#### 4. Procedures

a. Applicability Review. If a research design includes gathering data from or about living individuals, as described above, the PI will submit an Applicability Review Worksheet via email to the MCU IRB Vice Chair. The Vice Chair may provide recommendations for revision prior to submission to the Marine Corps IRB Chair for a determination about whether their proposed project meets the federal definitions of HSR and is subject to further IRB review. The review takes into account the purpose, methodology, recruitment methods, and risks of a project. It also requires that the PI submit the proposed data collection instrument (survey questions, sample interview questions, data fields to be requested, etc.). Although the project may still be evolving, the PI should be clear on the purpose, participants, and use of the data or the HSR determination may not be accurate.

b. Non-HSR Projects. If the Marine Corps' IRB determines that the project is not HSR, no further IRB review is required unless the scope of research changes. If that occurs, researchers must submit another applicability review. Even if a project is not HSR, MCU requires that researchers adhere to the same ethical principles of beneficence, justice, and respect for persons that underlie the IRB review process. This means ensuring that participants understand the purpose of a research project, how the information collected will be used, and whether they will be identified by name. See also Additional Review Requirements below.

c. HSR Projects. If the project is determined to be HSR, the PI will be asked to submit a full protocol and associated forms for review. This submission will expand upon the recruitment procedures, informed consent, and any risk mitigation steps taken to protect individuals and data. The PI also is required to complete an online training. Submission requirements and forms may vary based on details of the project. Researchers should consult with MCU's IRB Vice Chair.

d. Additional Review Requirements. Whether or not a project is determined to be HSR, there may be requirements for review by other Marine Corps or DoD offices depending on the details of the project. Additional information on these requirements is available from MCU's IRB Vice Chair.

e. Review Timelines. Planning and implementing human subjects research for many types of projects is manageable within the school year but must be started 60-90 days before recruiting participants or accessing data. The review process timeline depends on a number of factors: whether a study is found to be human subjects research, the potential risk to participants, certain categories of participants, and other factors. Certain projects also may be subject to additional Marine Corps and DoD review processes depending upon their scope, design, and intended participants. These reviews can increase the overall time it takes to get necessary approvals. MCU's Vice Chair can advise on the impact of various factors on review timelines.

f. Conducting HSR research. Any changes to elements of the approved IRB protocol must be submitted by the PI via email to the MCU IRB Vice Chair for IRB review. Any unanticipated problems or incidents must be reported promptly using the processes in reference (e).

g. Team HSR Research and Research Support Personnel. All personnel who will work on the project must be approved by the Marine Corps' IRB. The PI is responsible for the actions of all personnel associated with the project. It is essential to closely monitor the work done by any students, contracted research personnel, or other government employees on the project. Even if a researcher is a peer, the PI bears ultimate responsibility. Researchers and support personnel who are not Marine Corps employees (e.g., contractors) may need to complete an Individual Investigator Agreement to be included on an MCU project.

h. Cooperative HSR Research with Non-Marine Corps Partners. Research that is conducted in cooperation with investigators from an institution with its own IRB may require an agreement between the two IRBs. This agreement is captured in the Institutional Agreement for Institutional Review Board Review form.

i. Handling Data and Participant Information During HSR Research. Data and participant information must be handled in accordance with the standards set out in the protocol and informed consent agreement. In many cases, this means securing data in locked spaces and secure devices and systems. During travel, it may mean that one member of the research team retains positive control of files and devices at all times. Any error in handling data and participant information, even if quickly resolved, must be reported to the MCU IRB Vice Chair and Marine Corps IRB Chair immediately.

j. Project Closure. At the end of a project, PIs are expected to submit a final report via email to the MCU IRB Vice Chair using the forms and processes described in reference (e). The report must confirm that no further recruitment or data collection will take place and explain whether the data will be destroyed or retained for PI use or sharing with other researchers. The PI should attach electronic copies of any research outcomes including publications, reports, and presentations.

k. Record Retention. After project completion, certain records from the project as described in reference (e) must be retained for a total of 30 years. Records must be retained locally for a minimum of 10 years after which they may be retained locally for an additional 20 years or transferred to a Federal Records Center (FRC) in accordance with reference (e). MCU has established centralized HSR records storage to meet this requirement. Student PIs and military faculty and staff PIs are required to transfer their records to MCU's IRB Vice Chair prior to leaving MCU for retention in centralized storage. Civilian faculty and staff PIs may use MCU's centralized storage or retain the records and arrange for FRC transfer on their own. Faculty or staff members who leave MCU or can no longer provide appropriate storage for their HSR records must transfer records to MCU's centralized storage.

l. Monitoring and Audits. The Marine Corps Human Research Protection Program (HRPP) is authorized to monitor a PI to ensure compliance. Monitoring typically involves review of protocol records and observation of one or more instances of the consent process. The HRPP is required to audit a minimum of 10% of the protocols it handles each year. The audit typically involves review of protocol records and an interview with the PI regarding research conduct and record keeping. Audits also may be conducted "for cause" when there are known or suspected problems in research conduct.

m. Consequences of Noncompliance. The HRPP is authorized to suspend or close protocols when a PI is not in compliance with policy. It is authorized to restrict a researcher's use of data

gathered through research that was not approved or during research on an approved protocol when the PI has been found to be non-compliant. PIs and other research personnel who have been found to have problems with research conduct or compliance may be required to attend educational sessions addressing the areas of concern and develop a corrective action plan. MCU researchers who have been found to exhibit problematic research conduct or non-compliance may be barred from conducting HSR research for a period of time. Significant or repeated incidents of misconduct or non-compliance may also have consequences at the institutional level, restricting the ability of other faculty, staff, and students to conduct HSR.

Related Policies and Forms:

Research

Refer to the MCU Knowledge Management Portal for current versions of all policies, procedures and forms.

**Subsection 2 Contracting and Human Subjects Research**

Reference: (a) 48 CFR § 252.235-7004 - Protection of Human Subjects  
(b) MCO 3900.18 HRPP  
(c) USMC Human Research Protection Program Policy

1. Purpose. This section defines MCU policies and procedures that ensure compliance with the references, in particular the guidelines of the Marine Corps Human Research Protection Program (HRPP) within the context of contracted research support.

2. Overview. Defense Federal Acquisition Regulation System (DFARS) policy at reference (a) includes statutory and regulatory requirements for the ethical treatment of human subjects involved in research projects. Accordingly, USMC HRPP policies and procedures at reference (b) require the review and approval of contracted services that may meet the federal definitions for HSR.

3. Policy

a. Scope. Contracts for services that include data collection via interviews, focus groups, observation, surveys, or any other methods involving gathering information from or about people or analysis of identifiable data sets must be reviewed by the Marine Corps Human Research Protection Official (HRPO) during acquisition planning and ensure it meets compliance requirements detailed at reference (c).

b. Responsibilities

(1) Contracting Officer's Representative (COR). The COR is responsible for ensuring that a contract includes the required clauses for use in contracts involving human subjects research at reference (a) and coordinating review of the contract with the HRPO during acquisition planning. Subsequently, the COR should monitor compliance of the contractor with those clauses in the event that they execute services that may qualify as HSR.

(2) MCU IRB Vice Chair. The MCU IRB Vice Chair should have visibility of MCU requests coordinated with the HRPO and provide subject matter expertise in support of MCU contracting efforts that may involve HSR.

4. Procedures

a. During acquisition planning, a COR should contact the HRPO and MCU IRB Vice Chair via email to notify them that a contract is under development involving data collection via interviews, focus groups, observation, surveys, or any other methods involving gathering information from or about people or analysis of identifiable data sets.

b. During contract execution, the contractor will be expected to remain in compliance with the clauses at reference (a). The COR should monitor this compliance and ensure that any research activities have been reviewed and approved by the HRPO.

Related Policies and Forms:

Refer to the MCU Knowledge Management Portal for current versions of all policies, procedures and forms.

**Subsection 3 Approval/Endorsement of Research Using MCU Personnel, Facilities, or Resources**

- Reference: (a) 48 CFR § 252.235-7004 - Protection of Human Subjects  
(b) MCO 3900.18 HRPP  
(c) USMC Human Research Protection Program Policy  
(d) MCO 5300.18 Marine Corps Survey Program  
(e) MCU/EDCOM Policy Letter 1-21 Extramural Research

1. Purpose. In accordance with the references, this section defines MCU policies and procedures for gaining approval for research conducted by MCU students and personnel that will involve recruiting MCU employees or students as research subjects or using MCU data and/or requesting the use of MCU facilities and resources for conducting research. Extramural research, including research conducted by MCU personnel as part of their studies at another institution, is addressed in reference (e).

2. Overview. Researchers who want to conduct Marine Corps supported research, defined by reference (c), must demonstrate that they have obtained approval from commanders of units/organizations in which they plan to recruit participants and, in some cases, from the General Officer with oversight of their research topic. This requirement ensures that research conducted on government time and/or with the support of government resources (facilities, resources, or requirement) is not detrimental to mission achievement.

3. Policy

a. Scope. Per references (c) and (d), internal (faculty, student and staff) requests for research support and/or topic endorsement are reviewed by MCU to consider whether the research is supportable in terms of the facilities or resources requested, the time of the potential participants, and the impact of research activities on mission accomplishment. Reviews also may take into consideration whether the research benefits the participants and conflicts with, or is complementary to, other ongoing initiatives or research in the same subject area. Potential benefits to the Marine Corps also may be considered. However, because the Marine Corps is a public institution, reviews must be attentive to the fact that research of little or no interest to the service may have broader social and/or scholarly benefits. Additionally, reviews must take into account MCU's academic freedom policies when applicable.

b. MCU researchers will obtain approval from the vice president, director, dean, or equivalent (at the O-5/O-6 or GS-14/GS-15 level), for each school or directorate in which they will recruit research subjects or from which they will request data. Approval must be documented in a letter or email.

c. MCU researchers will request endorsement from MCU's commanding general only when required for review by the Marine Corps HRPP/IRB, Marine Corps Survey Program, or other external office.

d. If sufficient protections are not in place in the research plan to mitigate risk to MCU research participants or data, MCU may impose stipulations for approval. Such stipulations should be consistent with the principles of beneficence, justice, and respect for persons

underlying reference (a). Additionally, any MCU approval is contingent upon the review and approval of the Marine Corps' IRB and, when applicable, the Marine Corps' Survey Program.

c. Responsibilities

(1) Researcher. Per references (c) and (d), the researcher is responsible for providing all required submission elements for this review and conducting the research in accordance with the provided research plan. If requested, researchers should provide an after-action report and/or final research products to MCU.

(2) MCU IRB Vice Chair. The MCU IRB Vice Chair acts as the primary POC for coordinating research approvals/endorsement.

(3) School and Directorate Officials. Vice presidents, directors, deans, or equivalents (at the O-5/O-6 or GS-14/GS-15 level), as appropriate, may approve or disapprove research support requests to recruit subjects or access data within their units or to use facilities, resources or equipment necessary to achieving their unit's mission. Their review fulfills the local Commander (O-5 or O-6 level authority) approval requirement detailed at reference (c).

(4) President, MCU. President, MCU is the final authority for endorsement of a research topic under MCU oversight when required for review by the Marine Corps HRPP, the Marine Corps Survey Program, or other external review process.

4. Procedures

a. Researchers requesting MCU support or endorsement for their research should contact the MCU IRB Vice Chair to determine required materials and staffing processes that will apply to their project.

b. The MCU IRB Vice Chair will coordinate staffing to MCU's commanding general if required.

Related Policies and Forms:

Refer to the MCU Knowledge Management Portal for current versions of all policies, procedures and forms.

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