Functional Lead: Provost

Division: Research

Responsible Office: Director of Research

Reference: (a) Title 32, Code of Federal Regulations, Part 219, Protection of Human Subjects

- (b) U.S. Marine Corps Human Research Protection Program Policy and Procedures
- (c) Academic Regulations: Human Subjects Research
- (d) MCO 5300.18 Marine Corps Survey Program
- (e) MARADMIN 314/21 Paperwork Reduction Act Process for Controversial Survey Topics
- (f) DODI 3200.12 DOD Scientific and Technical Information Program
- (g) Academic Regulations: Public Access to Research and Data
- (h) Academic Regulations: Sponsored Projects
- (i) MCU/EDCOM Policy Letter 1-21 Extramural Research
- 1. <u>Purpose.</u> This section defines the required research reviews and the expectations and procedures for Marine Corps University (MCU) faculty, staff, students, contractors, and visiting researchers when conducting planning and research. (Those planning to conduct research for educational assessment and institutional effectiveness purposes also should consult the VPOP Regulations.)
- 2. <u>Background.</u> Research conducted by MCU's faculty, staff, and students is a critical part of the intellectual climate of the University and a part of many faculty and academic staff members' specified scholarly duties. Research brings new knowledge into the classroom and the hands of decision-makers and contributes to the reputation of the University. Additionally, the ability of MCU's faculty and research staff to build robust research agendas is an important factor in the University's approach to recruiting and retaining high quality personnel. MCU's schools and organizations support and manage research in different ways.

3. Policy

- a. Academic integrity and transparency
- (1) All research conducted by MCU faculty, staff, students, and contractors must be conducted in accordance with the principle of academic integrity.
- (2) To the maximum extent possible, researchers should strive to be transparent about their research efforts. Research transparency enhances the intellectual climate of the University, advances its outreach efforts by facilitating the exchange of ideas, and improves the discoverability of the work of MCU personnel. Transparency begins while research is ongoing through informal discussions with students and colleagues and more formal activities, such as presentations at conferences or symposia. Transparency once research has concluded continues to involve discussions and presentations, but also may include publication/dissemination of research results and, in some cases, sharing resources, such as bibliographies and data sets.

b. Research review requirements

(1) Research involving surveys, interviews, focus groups, observation, or personnel data. Per refs (a) and (b) Marine Corps University complies with federal law and Marine Corps policy regarding the protection of human subjects. Any project involving interaction with or observation of people or access to data about people must be submitted to the Marine Corps Human Research Protection Program (HRPP)/Institutional Review Board (IRB) to determine whether or not it is human subjects research. A researcher whose project is determined to be human subjects research must submit a protocol and other required materials to the HRPP/IRB for review and receive approval before starting any related research activities.

- (i) Marine Corps policy and procedures for human subjects research are established in reference (b).
- (ii) 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.
- (iii) Additional MCU policies are described below. Information on forms and procedures is posted on the MCU Knowledge Management Portal.
 - (iv) All submissions to the HRPP/IRB must be made through MCU's IRB Vice Chair.
- (v) Principal Investigators (PI) for human subjects research are responsible for the long-term storage requirements in reference (b). MCU has established a centralized storage capacity that is available as an alternative for PIs. PIs who are students, military faculty, or military staff are required to transfer all required records to MCU's centralized storage when their project is closed. PIs who are civilian faculty or staff have the option to use MCU's centralized storage. Any MCU PIs planning to leave MCU or who can no longer provide appropriate storage must transfer their records to MCU's centralized storage.

Refer to the Human Subjects Research section of the Academic Regulations for policy and procedures related to human subjects research. Additional information is available on the MCU website.

- (2) Research involving 10 or more people. Per ref (d), the Marine Corps Survey Program must review any project using survey, interview, or focus group methods when 10 or more individual participants will be recruited. MCU researchers must coordinate their submission through MCU's IRB Vice Chair. In addition to the review process described in ref (d), MCU researchers should be aware of several additional reviews that may be required as part of the Survey Program's process.
- (i) Research involving participants from more than one command will be sent to the Director of Marine Corps Staff for review. This process can take more than one month.

(ii) Research that seeks to gather information on topics deemed sensitive by the Survey Program, such as political affiliation of participants, may be sent to higher level review and counsel. These reviews can add several weeks to the review timeline.

- (iii) Research on the specific topics listed in ref (e) will be sent to the Office of Management and Budget for review. This process can take six to nine months.
- (iv) Research involving gathering information from the public, including retirees and DoD contractors, may also be sent for higher level reviews by both the Survey Program and the Marine Corps Human Research Protection Program. These reviews can take several weeks to several months depending on the offices involved.
- (3) Other review requirements. Research using certain methods or involving certain categories of participants may be subject to other Marine Corps and DoD review requirements. It is the researcher's responsibility to identify required reviews and take any necessary actions. Additional information about these requirements is available from MCU's IRB Vice Chair.
- c. Requirement for Public Sharing of Research Outcomes and Data. In accordance with references (f) and (g), outcomes from scientific or technological research funded in whole or in part by DoD (including salary) must be made available to the public. This requirement does apply to copyrighted works with provisions to allow researchers to comply with publication agreements. In some cases, data is also covered by the requirement. However, protected data from human subjects research may not be made public.
- d. <u>Data management plans and data</u>. Per reference (f) for some research projects, there also is a requirement to post a data management plan and research data to DTIC. Researchers should consult with MCU's IRB Vice Chair to determine if this requirement applies to their project.

e. External stakeholders

- (1) Formal external interest in MCU research may take different forms. In some cases, an outside Marine Corps or other organization may request research be conducted by MCU faculty, staff, or students. In others, the interest may arise during the design of the project or while it is being conducted. These expressions of interest or offers of sponsorship do not necessarily constitute tasking, but care should be taken to ensure that the researcher(s) and the external stakeholder have a shared understanding of the research process and planned outcomes.
- (2) Research outcomes that do not contain controlled information are publicly releasable, whether directly from the researcher(s), through publication, or through Freedom of Information Act (FoIA) requests. Agreements with external stakeholders should clearly state the researcher(s) intentions regarding release and circulation of research outcomes and potential future uses of data and reports. If the researcher(s) will produce outcomes solely for the use of the stakeholder and cede release decisions to the stakeholder, the details of this arrangement should be documented (e.g., will release of all research outcomes be determined by the stakeholder or just release of one or more specific outcomes, will the researcher have the ability to use the data for other scholarly or applied purposes, etc.).

(3) <u>Publication of research outcomes</u>. If the researcher(s) anticipate publishing research outcomes or expect that they may develop publications in the future based on data from the project, these expectations should be specified in the agreement with the stakeholder. Note that any publication requiring copyright must be developed in accordance with MCU's copyright policies.

- (4) <u>Control of data and research records</u>. As is common in academic settings, MCU researchers may maintain data, records, and other research materials for use and reference over the course of their careers. Researchers should specify their intent regarding these materials and also describe what access, if any, the stakeholder will have. Additionally, data and certain other records from projects involving human subjects must be protected in accordance with the policies described earlier in this chapter. These protections may preclude stakeholder access to data and certain other materials. If the research may involve human subjects, the possibility of restrictions on stakeholder access should be included in the documentation.
- (5) Resources and support. If the stakeholder will provide funds, logistical assistance, or other support, the details of the resources and support should be included in the documentation and the project must be submitted for review per reference (h). Additionally, if the researcher(s) will be devoting time or resources to the project that exceed what is considered normal for their positions, this should be documented, along with any required University approvals. For some projects, it may be necessary to document other expectations and agreements, such as project timeline, due dates for research outcomes, or required consultation sessions (see sponsored projects in the links below).
- (6) <u>Documenting agreements with external stakeholders</u>. External stakeholders may expect to have a stake in the research. It is critical that the researcher(s) and stakeholder(s) clarify and document expectations prior to agreeing to an arrangement. This documentation protects both the researcher(s) and the stakeholder. Documentation of the agreement may take any form appropriate to the project (email, letter, Memorandum for the Record, or Memorandum of Agreement), but should explicitly address the following topics:
- (i) <u>Stakeholder influence on design and review of results</u>. As is appropriate in an academic institution, most MCU research is conducted under the University's policies of academic integrity and academic freedom, meaning external stakeholders do not control the design and results will not be altered based on stakeholder concerns. This should be clearly stated in documentation. Alternatively, if these policies will not apply, the role of the stakeholder in influencing research design and results should be clearly specified. (Note: Projects in which researchers cede control of the project design and/or results to a sponsor can be perceived as violating scientific/scholarly integrity and reflect negatively on the researchers and the institution. Such agreements should be made only under special circumstances and should be carefully documented.)
- (ii) <u>Release of research outcomes</u>. Research outcomes containing classified or controlled unclassified information (CUI) must be handled in accordance with the policies applicable to the specific information category. It is the researcher's responsibility to determine applicable policies and required reviews. Additional information may be available from the University's Security Manager and/or Foreign Disclosure Officer. Research outcomes categorized as CUI must be marked with any required distribution statement and also should

include a statement regarding which exemption to the Freedom of Information Act (FoIA) supports restrictions on release.

- f. <u>External funds for research</u>. To accept funds from a different Marine Corps organization, other government agency, or non-governmental source, MCU faculty, staff, or students must follow MCU's Sponsored Projects Policy and procedures per reference (h).
- g. <u>Extramural Research</u>. Research is extramural when it is conducted by researchers or entities outside MCU who seek to (1) use MCU personnel, facilities, data, or other resources or (2) receive endorsement from MCU's commanding general for a broader project. Research conducted by MCU personnel as part of their studies at an external academic institution typically are categorized as extramural. Extramural research is governed by reference (i).
- 4. <u>Procedures</u>. Additional guidelines and processes related to research are posted on MCU's intranet and can be accessed through the Business Regulations intranet portal.

Related Policies and Forms:

Academic Freedom and Non-attribution
Academic Integrity
Use of Copyrighted Works
Faculty Council
Faculty Development
Faculty Regulations
Human Subjects Research
Professional Development Off-site Program
Speaker's Bureau
Sponsored Projects
Strategic Plan
Title 10 Employee Regulations

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