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TRAINING AND EDUCATION COMMAND
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USMC Human Research Protection Program (HRPP) Fact Sheet
Supporting Research: Command Considerations
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USMC HRPP Points of Contact

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This fact sheet applies only to projects that are under review by the USMC HRPP, which includes the USMC Institutional Review Board. If the project is being reviewed by the M&RA HRPP or the MCSC HRPP, contact those programs for information. Additional information and primary references are available on the USMC HRPP website.

Purpose: This fact sheet provides an overview of the requirements for letters of support for research and considerations for commands considering supporting human subjects research (HSR) with USMC personnel or data. As detailed below, the USMC HRPP defers to commands on many aspects of how researcher requests for support are processed and command decision criteria.

Requirement for letters of support – command and general officer / flag officer (GO/FO): Requirements for internal and external researchers conducting HSR to obtain support from commands are established in DoDI 3216.02 and USMC policy. The USMC HRPP uses letters of support to verify that researchers have complied with these requirements, ensuring commands have had the opportunity to make a decision regarding their capacity and willingness to support the research. Additionally, GO/FO letters of support are required for HSR conducted by external performers to ensure senior leaders in the Marine Corps have awareness of the research, are supportive of it, and can consider how it intersects with other ongoing and planned research.

What researchers should provide to commands when requesting support: The USMC HRPP advises researchers to provide commands concise information regarding the planned research activities, what they need from the command in terms of participation of USMC personnel, any logistical support they may need (e.g., scheduling rooms, help with base access, etc.), an explanation of risks associated with the research, and a description of the potential value of the research. Commands are entitled to require any information they need to make their decision. Commands also can reach out to the USMC HRPP with questions about a research project when considering whether to support it.

Common misunderstandings:

- Guaranteed outcomes: Commands should be skeptical of a research project that guarantees a particular outcome. If the outcome is already known, the research would not be necessary. All research involves uncertainty.
- Risk-free research: Commands should question claims that a project poses no risks. All research with humans involves some risk, even if slight. These risks are detailed in the research protocol and informed consent document.
- Requirement to support: Some funding sources may have titles including terms such as "Congressionally Directed," but there is no funding source or reviewing office that can compel a USMC command to make personnel available for HSR.
- Individual choice: All HSR must be voluntary. Even if a command issues a letter of support, each individual must be allowed to make their own choice about whether to participate. Commands can make information about projects available to their personnel, but may not engage in any activities that could influence individual choices. Commands must avoid any communication that could lead personnel to perceive that they are being "voluntold" to participate.
- Value of the research: DoD and academia sponsor basic and exploratory research as a necessary part of the scientific process that can lay the foundation for more focused research and development in the future. So, immediate utility of the expected research outcomes does not need to be a deciding factor. Commands are entitled to make their own decisions about which types of projects they will support.
- Meaning of "subject" in research: In HSR, participants are referred to as "subjects." This does not connote anything other than that the individual has made a voluntary, informed choice to participate in an HSR project.

Who can sign letters of support: All letters must be signed by the actual, not by an individual in an acting capacity or by direction. For flag officer letter, the signatory must be either (a) the first GO in the chain of command above all possible participants or (b) a flag officer or SES in the organization with oversight of the topic. For CO letters, the signatory must be the O-5 or O-6 in change of the unit from which participants will be recruited.

Letter of support format and content: The USMC HRPP does not require a specific format. Some commands use formal letters. Others use checklist templates to simplify the process. Regardless of format, the letter must include the title of the research (the same title used in submission to the researcher's Institutional Review Board), a clear statement that the command is willing to support the project, and a command point of contact with email and telephone number in case the USMC HRPP has questions. Letters may include any contingencies or requirements the command wants to communicate to the researchers. For example, some commands state that their ability to support research activities is contingent on mission requirements and the researchers clearing all required USMC reviews and require that researchers provide copies of research outcomes (e.g., reports, publications) to the command. Letters may be addressed to the researcher or to the USMC HRPP.

What not to include: Letters of support should not require changes in research plans. If a command is unwilling to support a project as stated in the research protocol, this should be discussed with the researchers prior to issuing a letter of support, as any changes may need to be approved by reviewing offices before implementation. Commands should not require access to data including identifiable

information. Similarly, commands should not require review of research outcomes prior to release or attempt to otherwise restrict dissemination of research findings. In addition to the general importance of free scientific inquiry, unclassified federally funded research is subject to policies that require public release of findings.

Staffing Order: USMC HRPP does not require that letter of support staffing take place in a particular order, e.g., CO first or GO/FO first. The purposes of the CO and GO/FO letters of support are different and involved units are not always be subordinate to the signing GO/FO. The USMC HRPP advises researchers to consult with commands about staffing processes, as there is significant variation in staffing preferences across the USMC. Some GO/FOs prefer to see that lower-level commands are able to support the research before making their decisions. Other GO/FOs prefer to make a decision before the project is staffed to lower-level commands. Others are comfortable allowing the processes to take place simultaneously.

Additional Command Considerations

The USMC HRPP reviews proposed HSR against specific criteria, largely focused on the risks and rights of individual participants. It is not authorized to restrict research activities to ensure all possible USMC questions or concerns are addressed. In additional to feasibility of support, commands also may want to consider other factors such as those listed below.

- **Operational security**: External researchers may not be aware of how information can pose operational security concerns for individuals or the command. Commands should ask questions about what information will be gathered (for both recruiting participants and as research data) and how information will be stored during and after the research.
- **Technology uses**: Technologies used in research (e.g., wearables, analytic software) may require participants or researchers to sign user agreements that give the technology company access and rights to information, including information that is gathered automatically, even if not needed by the researchers. While this is most obvious with personal devices, such as smart watches or phone and tablet applications, other technologies also raise concerns. Commands should ensure they are aware of and comfortable with the technologies. Additionally, many researchers allow participants to keep devices (e.g., wearables) after the research is complete. Commands should ensure they are aware of whether such devices will continue to be linked to the researchers and whether participants will be required to sign a new agreement to continue using the device.
- **USMC access to data**: While datasets produced in HSR are protected from disclosure, in some cases, de-identified versions of the data may be shared. If the data gathered in a research project may be useful for the USMC's own analysis, it is possible to arrange for the researchers to share them. Commands interested in accessing HSR datasets should consult with the USMC HRPP.
- **Future uses of data**: To reduce duplicative research, maximize return on investment, and reduce the research burden on participants, many funding sources encourage or require that researchers share their data, typically in de-identified format. This sharing can take many forms. Most commonly, researchers either retain the data and respond to individual sharing requests or deposit the dataset in a repository where it is accessible to a broad range of researchers. Commands should ensure they are aware of and willing to support such plans.
- **Commercialization of research data and outcomes**: Many grants and contracts support researchers to commercialize their research outcomes. Most USMC personnel will be familiar with this model in the context of technology research and development. However, it also can apply to other types of research. For example, large datasets of behavioral, psychological, physiological, or performance information or of opinions can have commercial value. Commands should ensure they are aware of and willing to support any plans for commercialization of USMC personnel's information.
- **Public affairs**: Some research addresses topics that are controversial. The USMC HRPP discourages commands from declining support solely because the results may be controversial, as research is important for informing debates and decisions on such issues. However, commands involved in research on potentially controversial topics may wish to consult with their public affairs office to ensure they can talk with researchers and prepare for inquiries.
- **Reason for using USMC personnel**: Marines are a highly desirable research population for many reasons, not all of which are related to the research. For example, a researcher hoping to develop a commercially viable outcome may seek Marines, special operations personnel, or other high-visibility military or sports populations for public relations and advertising purposes rather than because they are required to meet research objectives. Many such projects could be completed with other military or non-military populations. It is reasonable for commands to ask researchers if Marines are truly necessary for the research and consider the answer in their decision-making.

USMC HRPP Role

The USMC HRPP reviews human subjects research protocols to ensure the rights of participants are protected, to verify that the project is scientifically sound, and for other reasons associated with compliance with federal regulations and DoD, DON, and USMC policies governing HSR. USMC HRPP staff will make every effort to assist commands that have questions regarding specific research projects. However, the program is not staffed or resourced to assist researchers in pursuing letters of support. The USMC HRPP also has a role in taking action if something goes wrong with a research effort. If a participant is harmed or for other departures from the protocol, the researchers are required to contact their IRB and the USMC HRPP. Also, **if a participant or command has any concerns about how the research is being conducted or researcher behavior, they are encouraged to reach out to the USMC HRPP for assistance in addressing the situation.**

Other Required Reviews and Researcher Timelines

Researchers working with DoD personnel sometimes must navigate many reviews by different offices with different requirements and timelines. These reviews can affect their ability to be certain of when they will be able to execute the project. The USMC HRPP and USMC Survey Program can provide additional information if needed by commands.