UNITED STATES MARINE CORPS
TRAINING AND EDUCATION COMMAND
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USMC HRPP Fact Sheet
Human Research Protection Official (HRPO) Reviews

USMC HRPP Points of Contact

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Purpose of the HRPO Review: Required by DoD, DON, and USMC policies. To ensure that required DFARS clauses are included in all contracts and subcontracts, determine concurrence/non-concurrence with reviewing IRB's determination, address USMC-specific considerations, and ensure that the project has support from targeted units as required under USMC policy. This review is required even if your IRB or HRPP has determined that your project is not human subjects researcher is exempt. NOTE: HRPO reviews are conducted for projects directly funded by the USMC. If your project is not funded by the USMC, refer to the Fact Sheet on Administrative Reviews.

Baseline Requirements

1. Copies of contracts and, if applicable, subcontracts and statements of work showing the required DFARS clauses (252.235-7004). Contracts and subcontracts without the required clause must be modified to include it before submission for HRPO review. The contract documents must include tasks or other language indicating that it is intended to cover research of the sort being proposed.

2. If the specific research activity is not explicitly addressed in the contract, a copy of the statement of work, task order, or similar document showing either the specific research activities or a general category of research appropriate to the project. If you are not sure if the language in your documents is specific enough, contact the USMC HRPP to discuss.

3. Full package of materials reviewed by your IRB including the protocol, informed consent document/script, data collection instruments (e.g., survey questions, demographic questionnaires, samples of questions to be used in semi-structured interviews), and any other documentation required by your IRB, as well as the IRB's approval.
   - If adding USMC participants to an existing protocol via an amendment, ensure the submission includes the full, current, approved protocol incorporating any approved amendments.
   - If your project involves the use of commercial or in-development technologies (e.g., wearable devices or phone/tablet apps) that will require USMC personnel to sign a user agreement or otherwise agree to terms of use, you must provide a copy of the agreement/terms and a summary of what information the technology company will gather and what rights it will have to the information. Similarly, if your project involves the use of analytic technologies through which the company will have access to and retention or use rights for subjects' information or data, you must provide a copy of the user agreement/terms and a summary of what access and rights the technology company will have to information.
   - If your project was reviewed by a non-DoD IRB, include copies of your research ethics training (e.g., CITI classes) and documentation of the qualifications of the Principal Investigator and key research personnel.

4. For all non-exempt research, provide your organization's Federalwide Assurance (FWA) or DoD Assurance number and the reviewing IRB's OHRP registration number with expiration dates. Your IRB should be able to provide this information.

5. Letters of support from the Commanding Officers (COs) of any units from which you plan to recruit participants, request data, or request logistical or administrative support. Letters must be at the O-5 (LtCol) or O-6 (Col) level and must be signed by the actual or acting CO, not "by direction." For projects that will involve recruiting across many commands (such as service-wide surveys), contact the USMC HRPP to discuss options. Note: Letters from clinic directors or other individuals who are not in command of the USMC personnel being recruited will not be accepted. See also below.
   - The USMC HRPP does not require flag officer-level letters of support for projects funded by the USMC. However, other reviewing bodies, such as the USMC Survey Control Office, may require them.

Letters of Support

If your project has received a determination that it is not human subjects research and the USMC HRPP concurs, letters of support may not be required for HRPP approval, although other reviewing offices may require them. Even if no formal letters are needed, you will be required to conduct appropriate coordination with affected commands to ensure they are willing and able to support your project. If you believe this may apply to your project, contact the USMC HRPP to discuss.

It is the responsibility of the researcher to coordinate as needed to obtain letters of support. The USMC HRPP is not staffed or resourced to assist researchers with coordination or staffing.

There is no set format for the letters of support. Each command has its own preferences for format and staffing. However, each letter must include the title of the research (as listed in the IRB documents), a clear statement that the signatory is willing to support the research, and a command point of contact with email and telephone number.

When requesting a letter, provide information that allows the CO or GO to make an informed decision about whether it will be possible to support the project. This usually includes a short, clear description of the project and details regarding what support is being requested in terms of number of personnel, time away from main duties, what subjects will be asked to do, what will happen to the data you gather during and after the project, any concrete benefits to the USMC, etc. Also include any logistical or administrative requests, such as scheduling rooms, distributing study information, or helping the research team access base and find research sites. This is not the time to "pitch" your project. Information should be focused on what the command needs to know to determine the impact of the research on its personnel and main mission, which is how they determine if they can support it.

Tips for a Rapid and Successful Review

Budget time to get the required letters of support and ensure your submission is complete. If you are running up against a research deadline, contact the USMC HRPP to see if we can do a preliminary review of your materials while waiting for the letters of support. Preliminary reviews are conducted as a courtesy to researchers when HRPP time allows and are not a guarantee that no additional issues will be found during full review or that the submission will be approved.

Finding key information in the submitted materials is what takes the most time in the HRPO Review process. At the current time, the USMC HRPP does not require external researchers to fill out any special forms. However, that means extra time in our office sorting through what you submit to find what we need to review. **You can speed your review by providing the location of the key information below (file name and page number) in an email or separate document.** Much of this information also will be useful in requesting letters of support.

Key Information A: Basics
    1. PI name, title, organization, and contact information.
    2. If different from the PI, main POC name, title, organization, and contact information.
    3. Title of protocol and, if applicable, protocol number.
    4. Your organization's FWA or DoD Assurance number and IRB's OHRP number with expiration dates.
    5. Basic information on your IRB's review and approval:
- determination, expedited or exempt review categories, etc.
- protocol expiration date and/or the date a continuing review or progress report is required
- whether or not a waiver of consent or documentation of consent was granted.

    6. Basic description of the research.

Key Information B: USMC Support or Assistance Requested
    7. Information on the use of USMC participants:
- what installations or locations?
- what units or datasets?
- what characteristics do participants need to have (e.g., particular MOS categories, sexes, etc.)?
- how many participants do you plan to recruit?
- what will you be asking them to do and how long will each participant spend doing it?
- what demographic information or personally identifiable information about participants will you capture and will this information be used during analysis or in reports?
- when do you hope to gather the data? are you able to flex your times if units or participants are too busy?

    9. Information on other USMC support requested:
- are you requesting any logistical or administrative support from USMC organizations? (e.g., will you need rooms in which to recruit participants and conduct the research or assistance getting recruiting materials distributed?)

    10. Information on how and where participants will be recruited and examples of recruiting emails, flyers, etc.
- (*Note: The USMC HRPP is particularly interested in ensuring that that participants do not feel pressured by their leaders to participate or not participate. Organizational leaders should not be present at recruiting events or send messages regarding participation.*)

    11. User agreements or terms of use for any technologies subjects will be asked to use.
- As noted above, provide a summary of what information the technology will gather and what rights the technology company or developer will have to the information.

Key Information C: Location of Key Documents and Information
If your materials are combined in one or two documents or if your file names don't make it obvious what various documents are, consider including a short list that explains where to find key submission components.
    12. Full protocol along with any amendments, continuing reviews, or other documentation reviewed by your IRB.
- If you are adding USMC participants or data to a protocol that has been open for some time, it is very helpful if you can provide a summary of amendments and approvals to date.

    13. Informed consent documents and/or verbal script.
    14. Data collection instruments such as questionnaires, samples of interview questions, etc.
    15. Explanation of how the results will be used (e.g., for internal use by government officials only or will there be publications or presentations to other audiences?)
    16. IRB approval(s)
    17. CO support letter(s)
    18. Location of DFARS clause and description of research activities in contracts, subcontracts, and / or statements of work.

Ensure the submission gets to us. DoW email systems sometimes filter out messages from external senders or strip attachments. If you do not receive an acknowledgement of your submission within three business days, please reach out to us. It may be necessary to get the materials to us through DoD SAFE.

More information and primary references are available on the [USMC HRPP website](#).