



UNITED STATES MARINE CORPS
 TRAINING AND EDUCATION COMMAND
 2007 ELLIOT ROAD
 QUANTICO, VIRGINIA 22134

USMC HRPP Fact Sheet
Human Research Protection Official (HRPO) Reviews
updated 28 Mar 2024

USMC HRPP Points of Contact

Director, USMC HRPP and IRB Chair	HRPP Specialist and IRB Administrator
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HRPO contact information

All USMC-funded projects (except those funded by M&RA and MCSC)	Projects funded by M&RA	Projects funded by MCSC
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Note: This fact sheet provides information for individuals planning to submit their projects to the USMC HRPP’s HRPO. Individuals who plan to submit projects to the M&RA or MCSC HRPO must consult with those HRPOs for guidance.

Purpose of the HRPO Review: To ensure that required DFARS clauses are included in all contracts and subcontracts, determine concurrence/non-concurrence with reviewing IRB’s determination, address Marine Corps specific considerations, and ensure that the project has support from targeted units as required under Marine Corps policy.

NOTE: HRPO reviews are conducted for projects funded by the Marine Corps. If you project is not funded by the Marine Corps, refer to the Fact Sheet on Administrative Reviews.

Requirements

1. Copies of contracts and, if applicable, subcontracts showing the required DFARS clauses ([252.235-7004](#)). Contracts and subcontracts without the required clause must be modified to include it before submission to the HRPP.
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 HRPO to discuss.
3. Full package of materials reviewed by your IRB including informed consent documents, 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 (e.g., HIPAA documents). If adding Marine Corps participants to an existing protocol via an amendment, ensure the submission includes the full, current, approved protocol incorporating any approved amendments. Ensure that documentation of your IRB’s approval of all submissions is included.
4. For all non-exempt research provide your organization’s Federalwide Assurance (FWA) or DoD Assurance number and the reviewing IRB’s number with expiration dates. Your IRB should be able to provide these.
5. A list of all people who will work in research roles on the project (i.e., data gathering, data analysis, research support activities involving data, etc.) with the principal investigator and POC clearly identified and documentation of human subjects protection training for each.
6. 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 HRPP to discuss alternatives to the CO letters.

Letters of Support

There is no set format for the CO letters. Each command has its own preferences for format and staffing. Each letter must clearly state that the CO is willing to support the project, including any required logistical support. When requesting a letter, be sure to provide a short, clear description of the project and details regarding what support is being requested in terms of participant time and activities, as well as any logistical or administrative requests. This allows the CO to make an informed decision about whether or not it will be possible to support the project. It is the responsibility of the researcher to coordinate as needed to obtain letters of support. The USMC HRPP is not able to assist researchers with coordination or staffing.

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, it is fine to submit your materials for preliminary review while waiting for the letters of support.

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.**

Key Information A: Basics

1. USMC Program Officer or POC name, title, organization, and contact information.
2. PI name, title, organization, and contact information.
3. If different from the PI, main POC name, title, organization, and contact information.
4. List of all other people who will work in research roles on the project (i.e., data gathering, data analysis, research support activities involving data, etc.).
5. Documentation of human subjects protection training for the PI and all individuals listed in #3.
6. Title of protocol and, if applicable, protocol number.
7. Your organization's FWA or DoD Assurance number and IRB's number with expiration dates.
8. 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.
9. Basic description of the research.

Key Information B: Marine Corps Support or Assistance Requested

10. Information on the use of Marine Corps participants:
 - what units or locations 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 at your proposed time?
11. Information on other Marine Corps support requested:
 - are you requesting any logistical or administrative support from Marine Corps organizations? (e.g., will you need rooms in which to recruit participants and conduct the research or assistance getting recruiting materials distributed?)
12. 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. Organizational leaders should not be present at recruiting events or send messages regarding participation.)*

Key Information C: Location of Key Documents and Information

13. Full protocol along with any amendments, continuing reviews, or other documentation reviewed by your IRB.
 - If you are adding Marine Corps participants or data to a protocol that has been open for some time, it is helpful if you can provide a summary of amendments and approvals to date.
14. Informed consent documents and/or verbal script.
15. Data collection instruments such as questionnaires, samples of interview questions, etc.
16. 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?)
17. IRB approval(s)
18. CO support letter(s)

Ensure the submission gets to us. DoD email systems sometimes filter out forms that reference PII or HIPAA information because the filters confuse the blank forms with completed forms. 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.