

UNITED STATES MARINE CORPS

TRAINING AND EDUCATION COMMAND 2007 ELLIOT ROAD QUANTICO, VIRGINIA 22134

USMC HRPP Fact Sheet USMC IRB Vice Chair Responsibilities

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USMC IRB Points of Contact

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Guidance

The primary reference for USMC Vice Chairs is the USMC HRPP Policy and Procedures. References, templates, and other resources are available on the <u>USMC HRPP website</u>.

Purpose

IRB Vice Chairs have responsibilities in addition to those required of all IRB members. This fact sheet outlines those responsibilities. Vice Chairs should familiarize themselves with the relevant sections of the USMC HRPP Policy and Procedures.

Organizational Resource for Human Subjects Research

Ensure members of your organization are aware of your role. Conduct outreach and post information on relevant sites to ensure members of your organization are aware of the requirements for IRB review and oversight. Advise members of your organization on review requirements and processes and facilitate their navigation of requirements.

Preliminary Review of Submissions to the IRB

When an individual is ready to submit an applicability review, protocol, or protocol action to the IRB, conduct a preliminary review. Ensure all required information and materials are included. Ensure the information provided is clear. Make recommendations to the submitter for revisions if necessary. When required, facilitate staffing for letters of support. When a package is ready, submit the materials along with your recommendation (e.g., whether or not something is human subjects research or, for protocols, your assessment of risk level and possible review categories). Some vice chairs maintain a tracker of submissions and protocols, although this is not required by the IRB.

Keep Track of Open Protocols

Maintain awareness of all open human subjects research protocols in your organization. Assist the USMC IRB Administrator and PIs in ensuring that required reports are submitted on time.

Ensure PIs Maintain Required Records

Work with PIs to ensure that they maintain records required under the USMC HRPP Policy and Procedures. If a PI is leaving the organization or is unable to maintain the records, arrange for transfer to the IRB or an IRB-approved organizational repository. See also discussion of post-approval monitoring below.

Extramural Research

If your organization is sponsoring external researchers or allowing external researchers to conduct research within the organization, serve as an information resource for all involved to ensure required reviews are completed before research begins. For research funded by USMC, review by one of the service's three Human Research Protection Officials (HRPO) is required. For research not funded by USMC, administrative review by the USMC HRPP is required. When required, facilitate staffing for GO/SES endorsement. Assist the PI and the reviewer by ensuring that all required information and materials are included in the submission and making review recommendations.

DON HRPP Site Visits and Inspections

Participate in vice chair-specific meetings during DON HRPP site visits and inspections. Assist PIs in your organization with preparation for meetings with DON HRPP.

Additional Responsibilities

While not a routine part of most vice chair's work, the IRB Chair may request assistance with the following activities:

- Updates to policies and other program materials or processes provide input to ensure the program meets the needs of the organizations it supports.
- Monitoring the IRB Chair may request your assistance in executing the post-approval monitoring activities
 required under the USMC HRPP Policy and Procedures.

- Investigations the IRB Chair may request that you participate in or lead investigations into potential non-compliance, misconduct, or other problems. To help ensure that investigations are unbiased, you may be asked to participate in or lead investigations of incidents outside your organization.
- Second reviewer the IRB Chair may request that you provide a second set of eyes on submissions from outside your organization if the submission is from an organization without a vice chair.
- Independent reviews the IRB Chair may temporarily or permanently delegate authority for a vice chair to conduct applicability reviews or expedited reviews within their organization or across organizations.
- Acting IRB Chair when the IRB Chair must be absent for an extended period or is required to recuse themselves from a specific action within an IRB meeting, a vice chair may be asked to serve as acting chair.

Facilitating Other Reviews

As any experienced USMC researcher knows, review by the USMC IRB or USMC HRPP is not the only requirement for research to be approved. Whether or not a project is human subjects research, there may be a requirement for review by the USMC Survey Program and/or higher level reviews. Many vice chairs find its helpful to be knowledgeable about other review requirements and processes so that they can advise PIs. However, facilitation of other reviews is not a requirement of the USMC IRB.