# USMC HRPP Fact Sheet
# Basic Information for New USMC IRB Members and Alternates

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**USMC IRB Points of Contact**

| Director, USMC HRPP and IRB Chair | HRPP Specialist and IRB Administrator |
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**Guidance**

The primary reference for USMC Institutional Review Board (IRB) members is the USMC Human Research Protection Program (HRPP) Policy and Procedures. References and other resources are available on the USMC HRPP website.

**IRB Meeting Schedule and Logistics**

- Schedule: The IRB currently maintains a standing meeting on the last Wednesday of each month from 1330-1600 eastern. The exception to this is the November and December meetings, which typically are combined in single meeting in early December.
    - If no actions requiring a vote of the board are scheduled, the IRB Chair may cancel a meeting and defer items until the next month. This decision typically is made 1-2 business days before the meeting and you will receive notice via e-mail.
    - Meetings may be held at other times as necessitated by IRB business. However, the IRB Chair and Administrator make every effort to consolidate action items into regularly scheduled meetings.
- Logistics: Most meetings are held via Teams. 1-2 meetings per year are held in-person at MCBQ (notice of in-person meetings will be provided at least 30 days in advance). The IRB Administrator sends calendar events and agendas for meetings and sends an email in advance of each meeting to determine if enough members will be in attendance to establish a quorum for voting.

**IRB Climate**

IRB reviews of protocols and other matters are not simply compliance audits. The applicable guidance is broad and often requires interpretation to determine how it applies to specific protocols or protocol actions. Reasonable people can and do disagree during the board's discussions and votes. Board members are expected to speak and listen respectfully during discussions and make constructive contributions. Board members who disagree with the outcome of a vote are entitled to add an anonymous dissenting opinion to the protocol case file and meeting minutes. Board members who have concerns about the behavior of other members or HRPP staff or about the overall climate of the IRB can raise these concerns with the IRB Chair or the Institutional Official of the USMC HRPP.

**Accessing Materials**

The IRB uses the USMC HRPP SharePoint sites on the MCEN and EDU domains to share and store documents related to IRB operations. Board members have access to libraries that allow them view and download materials for upcoming meetings, as well as the library of past protocol records. The POC for access to the sites is the IRB Administrator.

**IRB Member and Alternate Member Routine Responsibilities**

- Block the routine meeting time on your calendar. Voting members are expected to attend all meetings except in unusual circumstances.
    - Alternates are expected to be available to attend when their organization's primary member is unavailable (if paired) and at other times if needed to establish a quorum.
    - Alternates are welcome to attend all meetings and are expected to attend at least three meetings per year, even if not required for quorum, in order to build and maintain familiarity with the IRB's procedures and portfolio.
- Conduct required CITI training and renew training before expiration date. Provide training documentation to the IRB Administrator.
- Maintain working knowledge of all applicable references and the current portfolio of protocols under IRB oversight.
- Prepare for each meeting by reviewing scheduled IRB actions and other meeting materials in advance.
- Respond promptly to scheduling and quorum emails.
- Report any conflicts of interest with items on a meeting agenda ahead of or during the meeting and recuse yourself from voting on that item.
- Review and vote on matters related to human subjects research in accordance with applicable law and policies.
- Participate in other IRB activities such as post-approval monitoring, investigations, policy and resource updates, and DON HRPP inspection meetings when requested by the IRB Chair.
- Serve as a resource in your organization for information on human subjects research and review requirements.

**Responsibilities to Your Organization and the IRB**

- When acting in your IRB role:
    - your primary responsibility is to the human subjects involved in research.
    - your input is needed on all IRB matters, not only those that bear directly on your organization.
- Most IRB members also serve as a central information source for IRB matters within their organizations. The IRB can help support these activities with fact sheets and other informational materials.

**IRB Member Roles in Facilitating External Research**

- Interaction with external researchers typically is handled by the IRB's vice chairs or the IRB Chair. In some cases, the USMC HRPP may request that IRB members assist external researchers in navigating some aspects of the review processes. For example, if an external researcher is seeking a letter of support from a CO or GO/SES in your organization, you may be asked to help them identify the right point of entry to get the request into the staffing process. Requests of this sort tend to be more common for members whose organizations do not have a vice chair.

**IRB-Related Roles**

For detailed descriptions of authorities and functions, refer to the USMC HRPP Policy and Procedures.

- Institutional Officials (IO). A senior official with various responsibilities for the establishment and operations of HRPPs and appointment of individuals into key HRPP and IRB roles. Reviews and approves or disapproves all non-exempt research. Each of the service's HRPPs has its own IO, each of whom is an SES. The USMC HRPP's IO is the only IO who can approve appointments to the USMC IRB.
- IRB Chair. The individual responsible for overseeing and managing the IRB, leading IRB meetings, and ensuring IRB and protocol records are retained as required. The IRB Chair may conduct applicability reviews and may approve protocols and protocol amendments for projects meeting the criteria for expedited review. (The current USMC IRB Chair also is a HRPO and EDO, see discussion of these functions below).
- IRB Administrator. The individual responsible for all administrative matters related to the functioning of the IRB, maintaining required records, and producing required reports. Serves as the primary POC for the IRB.
- Vice Chairs. Members of the IRB who have additional responsibilities associated with facilitating submissions from their organizations, advising PIs, etc. Vice chairs work with PIs in their organizations to ensure submissions are complete. They also make recommendations to the IRB Chair regarding determinations and review categories for submissions (from their own organizations and, when requested by the IRB Chair, from other organizations). If designated by the IRB Chair, vice chairs may conduct applicability reviews or expedited reviews independently. The IO or IRB Chair may designate a vice chair to serve as Acting IRB Chair if the IRB Chair must recuse themselves from part of a meeting or is absent.
- IRB Members. Voting members of the IRB with the responsibilities set out in the guidance described above.
- IRB Alternate Members. Members of the IRB with the responsibilities set out in the guidance described at the start of this fact sheet who vote only in the absence of the primary member (if paired with a primary member) or when designated as an alternate for another member by the IRB Chair. Categories of members for which each alternate may substitute are established in appointment letters.
- Consultants. Individuals asked to consult on submissions and/or engage in the IRB's discussions for specific issues based on subject matter expertise. Consultants do not vote.

**HRPPs and IRBs: An Overview**

BLUF: HRPPs are broader structures that include IRBs and other functions. Not all HRPPs have IRBs.

Any organization that seeks to conduct human subjects research must have an approved institutional assurance. DON oversees and approves all institutional assurances within the USMC and Navy. A human research protection program (HRPP) is the program established to manage activities, policies, and procedures related to human subjects research within the institutional assurance, but not all HRPPs have IRBs.

The USMC has three HRPPs: the M&RA and MCSC HRPPs, which cover their respective organizations, and the USMC HRPP, which covers the rest of the service. Only the USMC HRPP has an IRB. The other HRPPs rely on the USMC IRB. For most IRB members, the only visible indicator of the distinctions among HRPPs is protocol numbers. Protocols submitted from M&RA begin with "MRAMC," those submitted from MCSC begin with "MCSC," and all others start with "USMC."

HRPPs perform a number of functions beyond the IRB. Three additional functions of the service's HRPPs that are less visible to IRB members are:

- Human Research Protection Official (HRPO) Reviews. HRPO reviews are required for any research that is funded by the USMC and conducted by external researchers. The review must be conducted by an individual appointed by an IO to serve as a HRPO. These reviews involve assessing the protocol, the reviewing IRB's determination, and the contract or agreement under which the research is conducted. All three HRPPs have HRPOs appointed to conduct these reviews.
- Administrative Reviews. Administrative reviews are a unique USMC requirement. They are required for any project that is not funded by the USMC, but involves USMC personnel as subjects or participants and/or use of USMC data. Currently, these reviews are conducted only by the director of the USMC HRPP.
- Exemption Determinations. Determination that a protocol meets the criteria for exemption must be made by an individual appointed by an IO to serve as an Exemption Determination Official (EDO). Currently, only the USMC HRPP has an EDO, but other HRPPs are expected to appoint EDOs during FY25.
- Institutional Assurance Maintenance and Renewal: HRPP staff maintain the DON institutional assurance, which is what gives the IRB its authority to operate. This involves routine updates related to IRB membership and policies, submitting protocol records to DON, and other work related to compliance and administration. Additionally, HRPP staff handle most of the work related to DON's inspection of the program, its policies, and its records, which takes place across a four-year cycle leading to renewal of the assurance.