



UNITED STATES MARINE CORPS
TRAINING AND EDUCATION COMMAND
2007 ELLIOT ROAD
QUANTICO VIRGINIA 22134-5112

3900
HRPP
31 Jul 26

USMC HUMAN RESEARCH PROTECTION PROGRAM POLICY LETTER 02-26

From: Institutional Official, USMC Human Research Protection Program
To: Director, USMC Human Research Protection Program

Subj: APPOINTMENT OF BACKUP PRINCIPAL INVESTIGATORS FOR PROTOCOLS OVERSEEN BY
THE USMC INSTITUTIONAL REVIEW BOARD.

Ref: (a) 32 CFR 219
(b) DoDI 3216.02 (series)
(c) SECNAVINST 3900.39E (series)
(d) MCO 3900.18 (series)
(e) USMC HRPP Policy and Procedures

Encl: (1) USMC HRPP Interim Policy Change (Backup PIs)

1. Situation. In accordance with references (a) through (e), the USMC Human Research Protection Program (HRPP) reviews and oversees all human subjects research conducted or supported by the USMC. This includes Institutional Review Board (IRB) review and oversight of exempt and non-exempt human subjects research (HSR) protocols conducted by principal investigators (PI) employed by or assigned to the USMC and, when an appropriate agreement is established, HSR protocols conducted by others. In the past, DON HRPP allowed only a single PI for each protocol, meaning all research was required to stop when there was no PI to attend to supervise research activities. When a PI was furloughed or otherwise unavailable, this led to delays and, if contract support was used on a protocol, financial concerns. On 24 April 2026, DON HRPP notified the USMC HRPP that co-PIs and backup PIs are allowed. At the 29 July 2026 meeting of the convened USMC IRB, the board discussed this option and had no objections to implementing amending current policy to integrate this flexibility as addressed in Enclosure 1.

2. Cancellation. Not applicable.

3. Mission. The USMC HRPP allows backup PIs with appropriate limitations.

4. Execution

a. Commander's Intent and Concept of Operations

(1) Commanders Intent. The USMC HRPP establishes interim policy on backup PIs and integrates the policy in the next update to reference (e).

(2) Concept of Operations. At the discretion of the IO, IRB Chair, approving Exemption Determination Official, or convened IRB, a protocol may list a backup PI subject as described in Enclosure (1).

c. Coordinating Instructions. Not applicable.

5. Administration and Logistics

Subj: APPOINTMENT OF BACKUP PRINCIPAL INVESTIGATORS FOR PROTOCOLS OVERSEEN BY
THE USMC INSTITUTIONAL REVIEW BOARD

a. Administration

(1) Recommendations. Submit all recommendations concerning this policy to the USMC HRPP via the appropriate chain of command.

(2) Records management. Records created because of this policy shall be managed according to National Archives and Records Administration (NARA)-approved dispositions per SECNAV M-5210.1 CH-1 to ensure proper maintenance, use, accessibility, and preservation, regardless of format or medium.

b. Logistics. Not applicable.

6. Command and Signal

a. Command. This policy is applicable to all HSR overseen by the USMC IRB.

b. Signal. This policy is effective the date signed.

GRECO.ANTHONY. Digitally signed by
JOSEPH.JR.102457 GRECO.ANTHONY.JOSEPH.JR.
8441 1024578441
Date: 2026.08.05 16:35:51 -04'00'

A. J. GRECO, JR.

Distribution Statement A. Approved for public release: distribution is unlimited.

Appointment of Backup Principal Investigators for Protocols Overseen by the USMC Institutional Review Board

Enclosure 1 USMC HRPP Policy Letter 02-26 (Backup PIs)

The following administrative changes to the USMC Human Research Protection Program (HRPP) Policy and Procedures are made to address a recent DON HRPP decision that allows the appointment of Backup and Co-Principal Investigators (PI). Changes will be integrated in the next USMC HRPP policy update.

General

Sections of the Policy and Procedures referencing requirements for single PIs that are not addressed below must be brought to the attention of the USMC HRPP. In such cases, the USMC HRPP will provide supplemental guidance.

Chapter 7 Principal Investigator Roles, Responsibilities, and Process Guidance

Paragraph 1 revision. The sentences, “The IRB does not recognize Co-PIs. A single PI must be listed on the protocol submission.” are replaced with: “A single PI must be listed on the protocol. At the discretion of the IO, IRB Chair, approving EDO, or convened IRB, a Backup PI also may be designated in accordance with the limitations described in this chapter.”

Section 7.1(8) revisions.

The phrase, “may require that the PI designate a member of the research team to be the Acting PI in their absence.” is changed to read, “may require that the PI designate a member of the research team to serve as Backup PI in their absence (see section 7.3).”

The following sentences are struck, “The PI must notify the IRB when an Acting PI will be designated. Notification must include the name and full contact information for the Acting PI and the expected time period during which the individual will serve as Acting PI.

Section 7.3 is added.

7.3 Backup PIs and Co-PIs

If authorized by the IO, IRB Chair, EDO, or convened IRB, the PI may designate a qualified individual to serve as a Backup PI as outlined in this section. To minimize the potential for confusion regarding responsibility and authority, Co-PIs generally are not allowed. Individuals with a significant reason to designate a Co-PI rather than a Backup PI should contact the IRB Chair for guidance.

7.3.1 Intent of Backup PI Role

The intent of the Backup PI role is to allow research activities to continue during periods, such as furloughs, when the PI is not permitted to attend to PI responsibilities and other brief periods when the PI is unavailable. The Backup PI role is not intended to be used in cases where the PI is permanently departing the organization and there has been sufficient time to identify a new PI and submit amendment paperwork.

7.3.2 Required Qualifications of a Backup PI

The Backup PI must be a civilian government employee or service member assigned to the USMC. Contractors may not serve as Backup PIs. The Backup PI must have completed all training required for PIs and have sufficient qualifications, as evidenced by curriculum vitae or resume, to oversee the protocol. An individual selected to be a Backup PI must be an associate investigator on the protocol. The IRB Chair, EDO, or convened IRB may consider requests for designation of other qualified individuals on a case-by-case basis. Only the IRB Chair, EDO, or convened IRB (as applicable to the protocol) is authorized to determine whether an individual’s qualifications are sufficient and appropriate to serve as a Backup PI.

7.3.3 Designation of a Backup PI

A Backup PI may be designated by the PI in the initial protocol submission or by amendment. In unusual circumstances, such as the unexpected departure of the PI from the organization, the IO, IRB Chair, EDO, or convened IRB may consider a Backup PI designation request from the PI's organization. Written approval of the designation from the USMC HRPP is required before a Backup PI assumes PI responsibilities.

7.3.4 Notifications

The approved research team for the protocol must be notified within one business day of a Backup PI assuming PI responsibilities and notified within one business day of the primary PI resuming PI responsibilities.

The USMC HRPP must be notified in writing of the intent for a Backup PI to assume PI responsibilities. Except for actions required to protect subjects' rights and safety, the Backup PI may not assume PI responsibilities until the notification is acknowledged by the USMC HRPP other than as detailed in section 7.3.6. Notification must include the name and full contact information for the Backup PI and the expected time period during which the individual will serve as PI. The primary PI must resume PI responsibilities within 10 business days of returning to work / normal duties and notify the HRPP within two business days of resuming responsibilities.

The Backup PI must brief the returning primary PI on all actions taken during the primary PI's absence within 10 business days of the primary PI's return to work / normal duties.

7.3.5 Scope and Limitations of Backup PIs

When serving as PI, a Backup PI must be responsible for all activities conducted under the protocol, complete all required reporting, and ensure compliance with this Policy and Procedures and its references.

Subject to the notification requirements described in section 7.3.4, a Backup PI may assume PI duties at any time the PI is unavailable to oversee research activities, but is expected to return, such as furlough, detail, joint duty assignment, or leave periods. If the PI leaves the organization unexpectedly, a Backup PI may assume PI responsibilities until an amendment is submitted to designate a new PI.

A Backup PI must not serve as PI for longer than 40 business days (~ two calendar months) without approval from the USMC HRPP except as detailed in section 7.3.6.

7.3.6 Backup PIs During Furloughs

In the case of a furlough affecting both the PI and HRPP staff, the Backup PI must notify the USMC HRPP as indicated in section 7.3.4, but may assume PI responsibilities without receiving acknowledgement of the notification.

During furloughs that affect HRPP staff, Backup PIs must ensure that issues that may affect subjects' rights or safety, non-compliance, researcher misconduct, and other serious matters are delivered to the designated USMC HRPP point of contact for the furlough period. If that point of contact is not reachable or does not respond in a timely manner, the Backup PI must report the matter to DON HRPP. The Backup PI also must follow all guidance issued by the USMC HRPP regarding routine reporting, continuing review periods, and other matters during the lapse in appropriations.

When a Backup PI assumes PI responsibilities due to furlough of the primary PI, they may do so for the duration of the furlough plus 10 business days based on this policy without written approval or acknowledgement from the USMC HRPP.