United States Marine Corps

Human Research Protection Program Policy and Procedures

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1 Introduction

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1.1 Background

The protection of the rights and welfare of research volunteers is an acknowledged and accepted Command responsibility. This document details United States Marine Corps (USMC) specific procedures to ensure the protection of human subjects as stated in references (a) through (e) and based on the ethical principles described in reference (f). Constructive communication and dialog among all parties involved in the review and conduct of research involving human subjects is encouraged as a means of maintaining awareness of the importance of safeguarding the rights and welfare of human subjects. References (g) through (y) provide additional specific guidance as cited in this policy and procedure.

1.2 Assurance Requirement

Human subjects research (HSR) covered by this document shall be performed only by institutions or activities holding an appropriate institutional assurance of compliance from a Department of Defense (DoD) assurance approval authority. The Navy Surgeon General (SG) holds the Department of Navy (DON) assurance approval authority for new assurances, renewal of current assurances, and acceptance of other assurances. Key requirements of the DoD-Navy Assurance are completion of research ethics training, designation of an Institutional Review Board (IRB) to review research protocols, and the institution's plan for monitoring its HSR. HSR shall not be initiated until the institution holds a valid assurance for the protection of human research subjects, the research protocol has been reviewed by an authorized IRB, and approval for project implementation has been granted by an appropriate research approval authority.

1.3 Human Participant versus Human Subject

HSR is clearly defined in references (b), (c), and (d). In support of its mission, the Marine Corps carries out research activities that involve human participants. Research with human *participation* does not necessarily constitute HSR. Human participation requires safety involvement to ensure the safety of participants but may not require involvement of the IRB for human subjects protection. The IRB chair, with the assistance of an IRB vice chair, or other members of the IRB as designated and requested, will make the determination of whether the research meets the definition of HSR.

1.4 Conflicting Regulations

Issues pertaining to the protection of human subjects are constantly evolving, and there may at times be conflicts between applicable regulations. References (a) through (c) carry the force of law and supersede all other administrative regulations with regard to the protection of human subjects. In all cases, the regulation, instruction, or policy providing the greatest protection for the human subject shall prevail. Questions about resolving conflicts should be directed to the USMC Human Research Protection Program (HRPP) for resolution in consultation with the DON HRPP.

1.5 International Research

Research involving human subjects who are not U.S. citizens or DoD personnel, conducted outside the United States, and its territories and possessions, requires permission of the host country. The laws, customs and practices of the host country and those required in references (d) and (e) shall be followed.

1.6 Classified Research

Classified research with human subjects is held to the same ethical principles and human subjects protections as unclassified research and must receive prior approval from the Secretary of Defense (SECDEF) in accordance with reference (g). Classified research is not eligible for review under expedited review procedures as noted in reference (h).

1.7 Public Release of Information about the HRPP and Research Outcomes

To foster public trust in research and human subjects protections, information about the USMC HRPP and general information about specific projects is made available to the public, the news media, and Congress. This information may be released after appropriate review and approval per references (i), (j), (w) and other applicable guidance. Additionally, investigators may release research outcomes, such as reports, publications, and presentations, from HSR in accordance with their organizations' policies.

Under no circumstances shall participant information or data protected under an IRB-approved protocol be released to internal or external audiences beyond the approved research team and HRPP staff without IRB review and approval.

In accordance with references (x) and (y), outcomes from DoD research conducted using DoD funds must be made available to the public. For current and former DoD-affiliated individuals, prepublication review requirements in references (i) and (w) may apply.

1.8 Federal Funds

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of references (b) and (d) have been satisfied.

1.9 Compensation

DoD-affiliated personnel not in a duty status (e.g., normal off duty hours, reservists not on active duty) may be compensated for participation in research studies, but the compensation or any other incentive must not be extraordinary to eliminate possible undue influence of volunteers. Federal personnel (civil servants or service members) participating as human subjects in DoD conducted research while on duty (i.e., not on leave and participating during their duty hours) may not compensated except in limited circumstances per reference (d).

Principal Investigators should consult with other reviewing offices, such as the USMC Survey Program, as their policies on compensation may be more restrictive.

1.10 Vulnerability and Additional Protections

Additional safeguards shall be provided for subjects who may be considered vulnerable to coercion or undue influence because of their age, health, employment, financial status, or other

circumstances. References (c) and (d) require additional safeguards for prisoners, pregnant women, mentally disabled individuals, economically, or educationally disadvantaged individuals. Other groups warranting additional protection include severely ill patients, those in employer-employee status (worker), student-teacher, supervisor-subordinate relationships, or deployed active-duty personnel. Service members and their status as adults, for the purposes of legal capacity to participate in DoD-conducted or DoD supported research involving human subjects, is addressed in reference (d). Regardless of the risk level of the research, no senior personnel shall influence the decisions of their subordinates whether to participate as research subjects.

1.11 Captured or Detained Personnel

Research involving any person captured, detained, held, or otherwise under the control of DoD personnel (military, government civilian, or contractor) is prohibited. Such persons include: Enemy Prisoners of War, Civilian Internees, Retained Persons, Lawful and Unlawful Enemy Combatants. Such persons do not include DoD personnel being held for law enforcement purposes. Refer to references (c), (d), and (k) for regulations.

1.12 Surveys

Any project meeting the definition of survey in reference (u) requires review and approval or concurrence that it meets the exemption criteria by the Marine Corps Survey Program, per references (l) and (u).

1.13 Required Contracting Clause

Defense Federal Acquisition Regulation System (DFARS) policy addresses statutory and regulatory requirements for the ethical treatment of human subjects involved in research projects. Clauses for use in contracts involving human subjects in research were issued on 29 July 2009 to inform contractors of their responsibilities for compliance with references (a), (b) and (d); applicable DoD component policies, and when applicable Food and Drug Administration policies and regulations. Title 38, Code of Federal Regulations Part 207, Acquisition Planning; Part 235, Research and Development Contracting; and Part 252, solicitation Provisions and Contract Clauses were amended.

Any organization that may use contract support to conduct research involving humans or non-public personnel data must include the required clauses in the contract. Statements of work must be appropriate for the research being proposed.

Per reference (r), a DoD component sponsoring research involving human subjects must have a Human Research Protection Official (HRPO). The HRPO shall be identified in the DoD component's Human Research Protection Management Plan and shall be identified in acquisition planning. Refer to reference (r) for specific contractual language and clauses.

The responsibilities of USMC HRPOs are outlined in Chapter 6.

1.14 Conflict of Interest

1.14.1 Definition

Conflict of interest is defined as any situation in which professional, financial, or personal interests may compromise or present the appearance of compromising an individual's or group's

judgment in conducting, reviewing, approving, managing, and supporting research.

1.14.2 Action

Any investigators, key research personnel, IRB members, or other personnel must disclose all conflicts of interest, including any financial interests for themselves, spouses, and dependent children.

No person shall be involved in any review or approval of a protocol when there may be a conflict of interest, except to provide information requested by the IRB or HRPP. If the IRB chair is involved in a research protocol and a conflict of interest exists, they may not review or approve the research. An IRB vice chair must be appointed by the board or IO to review and approve actions related to the protocol and to lead any segments of IRB meetings in which the protocol is discussed.

If the IO is involved in a non-exempt research protocol and a conflict of interest exists, they may not review or approve the research. The next higher echelon in the HRPP approval authority chain of command or an alternate IO (if one has been appointed to serve within the institutional assurance) must review the research protocol.

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2 Guiding Principles

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The Marine Corps supports the ethical principles outlined in the Belmont Report (reference (f)), and has established its own ethical principles for human research, listed below.

2.1 Respect for Persons

Respect for persons incorporates at least two ethical convictions: first, individuals should be treated as autonomous agents; and second, persons with diminished autonomy are entitled to protection.

2.2 Beneficence

Beneficence involves two general rules: (1) do not harm, and (2) maximize possible benefits and minimize possible harms.

2.3 Justice

Justice requires that people are treated fairly; burdens and benefits are shared equitably. Subjects must be selected equitably, and vulnerable populations and populations of convenience must not be exploited.

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3 Organization, Authority, and Delegation

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3.1 Human Research Protection Organization in the USMC

Reference (t) provides service-level policy regarding organization, authority, and roles related to human subjects research. Figure 3-1 illustrates the service structure. In summary:

The USMC Coordinating Official establishes service-level policy related to human subjects research, ensures coordination across the service's HRPPs, and makes decisions regarding any requests to submit proposals to DON HRPP to establish additional HRPPs or IRBs.

The USMC currently has three HRPPs. The Manpower and Reserve Affairs (M&RA) HRPP addresses human subjects research matters originating within or funded by M&RA. The Systems Command (MCSC) HRPP addresses human subjects research matters originating within or funded by MCSC. The USMC HRPP addresses human subjects research matters originating within or funded by all other USMC organizations. All three HRPPs have HRPOs and are entitled to appoint Exemption Determination Officials (EDOs). The USMC HRPP includes the service's only Institutional Review Board (IRB) and has agreements with the other HRPPs to provide IRB services for their projects. The other HRPPs provide s to the IRB. The USMC HRPP also conducts all Administrative Reviews for the service. Each of these roles and functions is addressed in greater detail in this policy and procedures.

Except where otherwise noted, this policy and procedures applies to the USMC HRPP and USMC IRB. Other HRPPs in the service have their own policies. Because the other HRPPs rely on the USMC IRB, the sections of this policy and procedures addressing IRB-related matters and USMC-conducted human subjects research apply to the entire service.

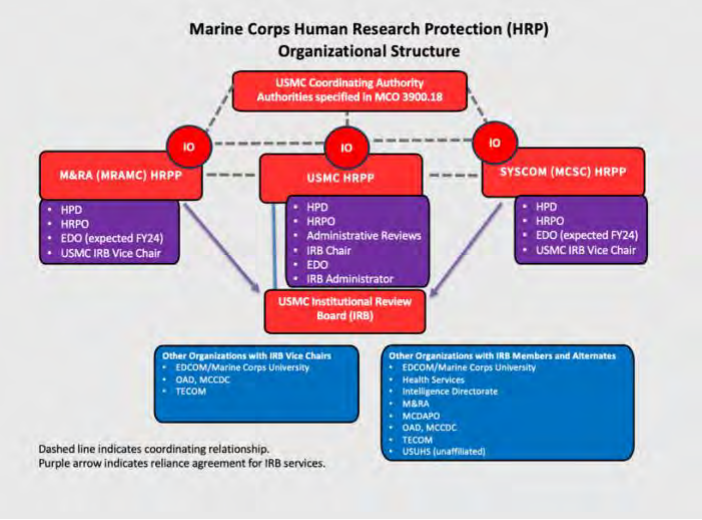

Figure 3-1. Marine Corps Human Research Protection (HRP) Organizational Structure and Functions

3.2 USMC HRPP Human Protections Director and other Staff

The USMC HRPP is managed by the Director, USMC HRPP who serves as the Human

Protections Director (HPD) and is the primary contact for the USMC HRPP. This individual typically also is appointed to serve as the USMC IRB Chair and as a HRPO and EDO.

The USMC HRPP staff roles also include IRB Administrator, Assistant Program Manager, and Knowledge Manager. These roles may be combined in one position or split among multiple Support Personnel. An individual performing these roles may also be appointed to serve in other roles such as HRPO and/or EDO. The USMC HRPP may add roles and/or positions as needed to comply with applicable policies and ensure the efficient operation of the program.

3.3 Delegation of Authority

1) In accordance with reference (e), the Secretary of the Navy delegates the authority and responsibility for the DON HRPP to the Navy Surgeon General (SG), except for those authorities and responsibilities specifically retained by the Secretary of the Navy and those delegated to the Under Secretary of the Navy.
2) The Navy SG may delegate to Commanders, Commanding Officers, and Officers in Charge the authority to approve HSR protocols under their respective cognizance through an approved DoD-Navy Assurance for the Protection of Human Research Subjects. The Institutional Official (IO) can also serve as a Commander. Per reference (t) the Executive Deputy, Training and Education Command (CG TECOM) serves as the coordinating authority for the HRPP within the Marine Corps.
3) Per reference (t) the CG TECOM has designated the Executive Deputy, TECOM to act as the Institution Official (IO) with responsibility for oversight of USMC HRPP. The USMC IO is tasked to establish, operate, and maintain the Marine Corps service-level human research protection program to support HSR requirements for the Marine Corps. This includes establishing the USMC HRPP (HRPP) and USMC Institutional Review Board (IRB).
4) The IO may delegate to the IRB chair and vice chairs authority to conduct applicability reviews and to review and determine that research is eligible for expedited review, and to suspend research due to adverse events involving subjects or others, significant deviation from approved protocols, or for reasonable cause. The IO may delegate to the IRB chair and others the authority to serve as Exemption Determination Official. Appendix G addresses the process for delegation of IRB responsibilities and authority to conduct HRPO Reviews and Administrative Reviews.
5) This authority may not be further delegated.

Figure 3-2 illustrates the authority delegation for the DON HRPP. In addition, Figure 3-1 shows the communication flow between the DON HRPP, the Marine Corps IO, the IRB, and research personnel.

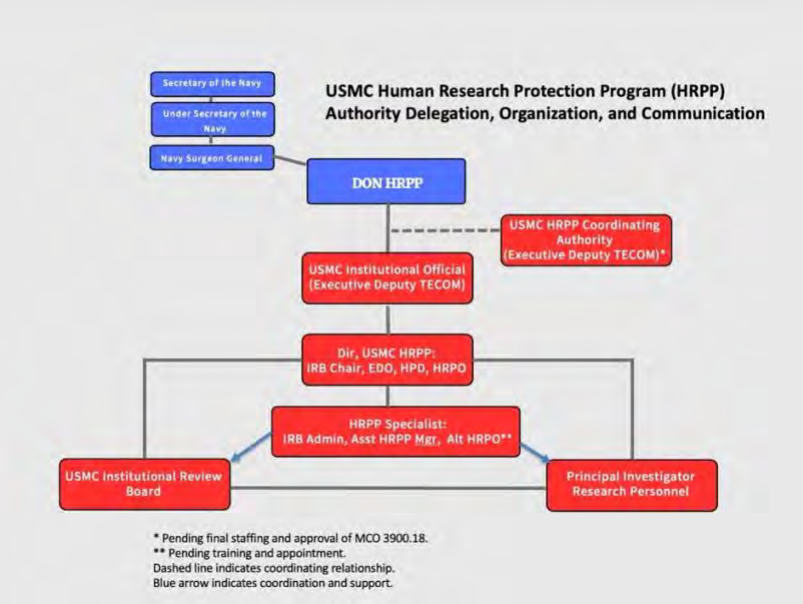

Figure 3-2. Authority Delegation, Organization, and Communication Flow within the USMC HRPP

6) Except when prohibited by applicable laws or higher-level policies, the Director of the USMC HRPP or the USMC IRB Chair, with the approval of the USMC Coordinating Authority, IRB, or IO as appropriate, may make exceptions to the USMC HRPP Policy and Procedures and other internally developed guidelines to address unusual or urgent situations, to streamline processes, or for other reasons. Such exceptions shall be included with the documentation entered into the records of the affected protocol or, if no protocol is involved, documented in other appropriate HRPP and/or IRB records.

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4 USMC Institutional Official and IRB Roles and Responsibilities

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4.1 DoN and USMC Personnel

All Navy and Marine Corps personnel conducting, supporting, reviewing, approving, or managing HSR shall view the protection of human subjects as an important command issue at all echelons, both ashore and afloat. Commanders, Commanding Officers, Officers in Charge, IOs, heads of activities, scientific and technical program managers, project directors, IRB members, IRB support staff, and investigators shall maintain concern for the safety and welfare of volunteer subjects.

4.2 USMC Institutional Official

The Executive Deputy, Training and Education Command (TECOM) serves as the IO for the USMC HRPP.

The USMC IO also has overall responsibility for the conduct of the USMC HRPP for all Marine Corps commands and organizations not having their own Institutional Assurance.

The USMC IO shall:

1) Complete and document initial education and training prior to taking any HRPP-related action and comply with requirements for continuing education and training.
2) Ensure initial and continuing education and training for all personnel involved in the conduct, review or approval of research involving human subjects, commensurate with their roles.
3) Appoint in writing the USMC IRB's chair, vice chairs, and members and any EDOs, and/or HRPOs serving under the USMC assurance, ensuring each individual has appropriate qualifications and experience. (See Appendix K.)
4) Ensure submission (by HRPP staff as assigned) of appropriate documentation for HRPO and EDO appointment letters, to Director, DON HRPP.
5) Inform Director, DON HRPP when there are significant changes to the institution's policies or when there is a change in the IRB chair or IRB membership.
6) Ensure any individual designated to make a determination (e.g., HRPO, IRB chair, EDO, vice chair) regarding research or exempt status does so in accordance with procedures codified in this HRPP Policy and Procedures.
7) Provide the resources, workspace, technology, and command technical and administrative support needed to ensure compliance with this policy and associated higher-level guidance.
8) Establish and maintain policies and procedures to provide adequate oversight, including authority to suspend or terminate research involving human subjects.
9) Ensure the establishment of a system to maintain research files, HRPP correspondence, IRB records and HRPP-related determinations (e.g., HRPO, EDO) per reference (m).

10) Establish and maintain a DoD-DON Assurance and other federal assurances, if appropriate.

11) Submit new and renewal assurance documentation to the Director, DON HRPP for processing.

12) Identify on the USMC DoD-DON Assurance all IRBs that are part of the institution, or any IRBs not part of their institution that the USMC will use to review research.

13) Ensure the proper functioning of any IRB established under this assurance in accordance with reference (e).

14) Ensure the IRB submits to DON HRPP all required documentation, such as copies of protocol actions, meeting minutes, and required reports.

15) Evaluate and improve the USMC HRPP annually.

16) Fulfill all other IO duties in accordance with reference (e).

In reviewing non-exempt research, the IO shall:

1) Consider IRB-approved research to ensure it is in alignment with the mission of the command and that the command has the resources to carry out the project successfully.

2) Review, at a minimum, the following actions for each non-exempt protocol. (The IO may choose to review a greater range of actions for specific protocols through verbal or written arrangement with the IRB chair):

    a. Initial review.

    b. Amendments involving changes bearing on the IO's approval criteria (e.g., additional of new USMC research sites, extension of research timeline, or significant changes to research objectives).

    c. Results of the IRB's investigation of potential serious and/or continuing non-compliance.

    d. Results of the IRB's investigation of potential UPIRTSOs or adverse events.

    e. Suspensions or terminations of previously approved research by the IRB.

    f. Other actions if recommended by the IRB chair.

3) Review and forward to the Director, DON HRPP research which may require higher-level approval or waivers (by UNSECNAV, SECNAV, ASD(R&E) or SECDEF) before the research may begin.

The IO shall not:

1) Approve research that has been disapproved by the IRB.

2) Exert undue pressure on a duly considered research study approved by the IRB.

4.3 IRB Positions and Responsibilities

4.3.1 Chair, IRB

The USMC IRB Chair and vice chair(s) acting in a USMC IRB Chair capacity shall be a federal employee or Service Member. The IRB Chair may also be assigned as the HRPP Director for the Marine Corps. As the HRPP Director, the Chair provides support to the USMC IO and is the primary source of information concerning HSR policies.

1) May serve as the IRB Administrator.
2) Complete and document initial and continuing research ethics and human subjects protections training. Ensure all members of the IRB, investigators, and appropriate IRB support personnel have completed appropriate research ethics training.
3) Conduct preliminary reviews to determine:
    a. Whether the proposed study meets the definition of research as defined in reference (b).
    b. Whether the proposed study meets the definition of HSR as defined in reference (b) and (d).
    c. The level of research risk associated with protocols.
    d. Whether a protocol meets criteria for exemption. If found to meet criteria for exemption, if appointed as an EDO, the IRB Chair shall provide a written determination for the research as outlined in Chapter 14 of this USMC HRPP Policy and Procedures.
    e. Whether a protocol meets criteria for expedited review.
    f. For IRB Action Requests that will require convened IRB review, which are submitted less than 10 business days prior to the scheduled IRB meeting, the IRB Chair may consider a request for exception to the submission timeline outlined in paragraph 7.2.3 of this policy. If the IRB Chair determines that there is justification for presenting the IRB Action Request to the convened IRB, with less than 10 business days notice, the Chair shall notify both the IRB and the PI that the action will be considered and shall document that determination in both the IRB minutes and in submission to the respective IO for approval. The convened IRB shall make the determination whether the board had sufficient time to review the protocol action and whether to take action or table the protocol determination for the next scheduled convened board meeting.

1) Review non-exempt HSR research protocols that meet criteria for expedited review procedures. Inform all IRB members of the results of expedited reviews.
2) Conduct concurrence determination of HSR applicability reviews, or may delegate this to a vice chair.
3) Monitor continuing HSR for protocol changes.
4) Suspend research until the convened IRB can review the protocol due to an UPIRTSO, or serious adverse events, significant deviation from approved protocols, noncompliance or

for other reasonable cause.

5) Assign applicability reviews and research protocols to appropriate vice chairs for review.
6) Periodically brief the IO on the status of IRB activity and active protocols.
7) Ensure the IRB is informed of all ongoing HSR.
8) Ensure that determinations and reviews for HSR projects made by EDOs, the IRB Chair, or vice chairs are provided to the convened IRB for situational awareness or endorsement as appropriate and that reviews (as described in section 4.2) of non-exempt HSR are routed to appropriate IO for review and approval or disapproval.
9) Ensure that the IRB reviews research in accordance with the Common Rule, DoD, DON requirements, FDA requirements as applicable, and that it considers scientific review as required for non-exempt HSR research.
10) Review and sign IRB meeting minutes.
11) Ensure that minutes and approval or disapproval of research protocols are appropriately documented.
12) Consult with other committees and individuals as appropriate or necessary (e.g., radiation safety, safety, biosafety, security, privacy board, legal officer).
13) Manage Research Monitoring activities as described in Appendix E and Institutional Effectiveness activities.
14) Provide prompt notification of subparagraphs (a) through (f) below to the IO whose institution is conducting the research and to the Director, DON HRPP. Upon completion of investigation, submit reports within 15 business days (including supporting documentation, information, review, disposition, recommendations, and associated plans for corrective action) for the following:
    a. All investigations and audits of the institution's HRPP, including those conducted by outside organizations (e.g., FDA, OHRP).
    b. UPIRTSOs
    c. Initiation and results of investigations of serious or continuing non-compliance.
    d. Initiation and results of investigations of research misconduct.
    e. Suspensions and terminations of previously approved research protocols
    f. Significant communications between the institution and other federal departments or agencies, state agencies, or foreign governments regarding compliance and oversight.

4.3.2 Vice Chair, IRB

1) Serve as acting IRB Chair in the absence of the Chair.
2) Complete and document initial and continuing research ethics and human subjects protections training.
3) May serve as the IRB administrator.

4) Perform the duties identified as a Member, IRB.

5) When appropriate conduct concurrence determination of HSR.

6) Participate in Research Monitoring activities as described in Appendix E and in Institutional Effectiveness activities.

7) Conduct preliminary review of all USMC and external/extramural projects that will be submitted to the HRPP via their organization. Ensure submission completeness and provide review considerations and/or recommendations to the HRPP.

4.3.3 Administrator, IRB

1) In the current USMC HRPP staff structure, the IRB Administrator role is included in a position that encompasses multiple roles. To maximize efficiency, systems and processes established by the IRB Administrator may be used for other USMC HRPP needs when appropriate. For example, systems for managing submissions may include both IRB-related submissions and other types of submissions handled by the USMC HRPP and work on the IRB sections of the program's website can be combined with work on other sections.

2) The IRB Administrator shall

    a. Be the primary interface between investigators and reviewing officials (USMC IRB Chair and vice chairs, IRB members, the USMC HRPP's EDO, the USMC HRPP's HRPOs) and between the USMC IRB and HRP POCs at other USMC institutions.

    b. Complete and document initial and continuing research ethics and human subjects protections training as required for the role.

    c. Serve as the primary POC for questions from IRB members, PIs, and external individuals with questions about the IRB and human subjects research.

    d. In compliance with references (b), (d), (e), and (m), establish, maintain, and update systems and records to ensure the efficient, accurate, and orderly management of all matters related to the IRB. Specific records duties include, but are not limited to:

        i. Maintain a log of all submissions to the IRB, assigning a formal tracking number to each and tracking each submission through the review process.

        ii. Maintain documentation of all applicability review determinations and protocol actions to facilitate routine operations.

        iii. Maintain records of required training for research personnel on all open protocols, IRB members, and HRPP staff. Provide renewal reminders to individuals as needed. Advise IRB Chair of instances of delinquent training requirements.

        iv. Ensure protocol actions and other IRB discussion items, decision items, and updates are added to the agenda for the next meeting to present to a

convened IRB.

v. Ensure all required records of applicability reviews, protocol actions, and IRB operations are submitted to DON HRPP (when applicable) and archived appropriately.

vi. Ensure all required records of appointments to the IRB are submitted to DON HRPP as institutional assurance updates and archived appropriately.

vii. Maintain records of IRB member and staff qualifications, rosters, and related information as required by policy and to support the needs of the IRB and its members.

e. Support the operation of the IRB. Specific duties include, but are not limited to:

i. Coordinate IRB events and meetings, including scheduling, establishing agendas, arranging for rooms, organizing materials for review, ensuring board member access, issuing calendar events and reminders, and conducting other administrative tasks associated with events.

ii. Take attendance and minutes in convened IRB meetings and produce the formal meeting minutes for review by the IRB Chair.

iii. Submit required paperwork to DON HRPP when there are changes to the IO, IRB Chair, vice chair(s), and members, or when changes are made to documents supporting the Institutional Assurance.

iv. Participate in Research Monitoring activities as described in Appendix E

v. Develop or assist in the development of informational content and materials, SOPs, instructions, policies, and other materials.

vi. Maintain IRB information systems/platforms (internally and externally focused), dashboards, trackers, and websites, to facilitate the ability users to locate and use information they need and collaborate when needed. Ensure information systems are organized to support different categories of users such as USMC HRPP staff, IRB members, USMC leadership, PIs, and external audiences.

vii. Coordinate site inspections and other meetings with external stakeholders.

viii. In coordination with the IRB Chair and, if applicable, other USMC HRPP staff, design and conduct activities to assess the program's effectiveness. Report on the results of assessment activities at least annually.

ix. Develop and maintain relationships with stakeholders and other DoD and civilian IRBs sufficient to ensure appropriate information flow and coordination.

x. Assist the IRB Chair in the day-to-day operations of the IRB.

xi. Inform the IRB Chair and/or IO of events and concerns affecting the IRB.

f. Support PIs. Specific duties include, but are not limited to:

i. Monitor the approval periods of protocols and notify the IRB Chair and PI of upcoming protocol due dates for required submissions such as Continuing Reviews and Progress Reports.

ii. Assist in the execution of Individual Investigator Agreements (IIA) and Institutional Agreements for IRB Review (IAIR), when required.

iii. Identify and analyze friction points between PIs and the IRB, propose solutions to the IRB Chair, and implement solutions.

iv. Ensure informational materials and communications sent to PIs are audience-appropriate.

g. Perform other duties assigned by the IO or USMC HRPP Director/IRB Chair as needed.

4.3.4 Members and Alternate Members, IRB

1) The primary role of the IRB member or alternate member is to protect the rights and welfare of human research subjects in accordance with federal, DoD, and DON requirements. Additionally, members and alternate members shall:

a. Serve as a resource in their organization for questions regarding human subjects research review processes and requirements.

b. Complete and document initial and continuing research ethics and human subjects protections training.

c. For research originating within their organization, or when appropriate, conduct initial HRPP review to determine if protocol meets the definition of HSR and submit for concurrence from the IRB Chair or, when applicable, vice chair.

d. Ensure that PIs within their organization submit protocols for projects that meet the definition of HSR to the IRB Administrator for coordination and initial review.

e. Participate in Research Monitoring activities as described in Appendix E and in Institutional Effectiveness activities.

f. As needed, participate in activities and meetings associated with required inspections (or similar) by DON HRPP and other authorities.

4.3.5 Scientific/Scholarly Reviewers

Review each assigned human subjects protocol application, typically only protocols expected to be non-exempt, for scientific merit or scholarship per the Marine Corps standards as established in Chapter 19 of the HRPP Policy and Procedures or by other appropriate criteria for scientific review before forwarding it for IRB review using the Scientific/Scholarly Review Template.

4.3.6 Research Ombudspersons.

Complete required initial and ongoing research ethics training including human subjects protection training and perform duties as specified in the protocol(s) they are supporting.

4.3.7 HRPP Support Personnel and Organizational Points of Contact

1) HRPP Support Personnel or Organizational Points of Contact (POC) may be designated by commands and assigned duties based on command requirements and the policies and practices of the USMC HRPP. HRPP Support Personnel also may be designated within the HRPP to support the program. HRPP Support Personnel or Organizational POCs may be required to

    a. Advise PIs regarding protocol submission requirements.

    b. Serve as the primary interface between their command and the USMC HRPP.

2) HRPP Support Personnel working within the USMC HRPP may be assigned specific duties under a position description or contract. They also may be required to provide general assistance the USMC HRPP Director and other positions in managing day-to-day operations of the HRPP, records and knowledge management tasks, and special events or projects.

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5 Exemption Determination Official (EDO)

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An EDO shall be a federal employee or service member designated by the institution's IO to review proposed efforts. The IRB Chair is appointed as an EDO for the USMC HRPP.

The EDO shall:

1) Complete and document initial and continuing education and training prior to performing any HRPP related duties.
2) Review protocols, test plans, proposals, and other activities to determine if the proposed effort meets the definition of research involving human subjects and if so, whether research is eligible for exemption from the certain provisions of this policy as set out in Chapter 14.
3) Document determination and, if applicable, include exemption category and rationale.
4) Submit determinations and supporting materials to the Director, DON HRPP for headquarters-level administrative review and to the IRB as indicated in Chapter 11.
5) Advise the Principal Investigator (PI) and research sponsor of determination(s) and if the research is not eligible for exemption, recommend that the PI or research sponsor refer the effort to an IRB for further disposition.
6) Maintain records of determinations. Ensure records are available for site inspections and assist visits.

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6 Human Research Protection Official (HRPO)

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The HRPO shall be a federal employee or Service Member designated by the institution's IO to review proposed efforts.

The HRPO shall:

1) Complete the required initial and ongoing research ethics training, including human subjects protection training.
2) Conduct timely review of documentation submitted by non-DoD institutions in accordance with the terms of Defense Federal Acquisition Regulation Supplement (DFARS) 252.235-7004 (see reference (r)) or comparable language for grants, assistance agreements, CRADAs and other agreements.
3) Provide guidance regarding the potential need for additional oversight, human research protection review and approval requirements prior to award and execution of research involving human subjects.
4) Review the Assurance of compliance and IRB approval submitted by the contractor and verify that the Assurance is appropriate for the research as stated in the Statement of Work.
5) Review the protocol and the contractor's IRB approval for compliance with DoD, DON and Marine Corps policies.
6) Confirm that the contractor's determination that the proposed research is not research involving human subjects.
7) Confirm that the contractor's determination that the proposed research meets an exemption criteria in 32 CFR 219.104 is correct.
8) If the HRPO does not concur with or accept the contractor's IRB's determination or finds that there are concerns regarding compliance with regulations or USMC policies, the HRPO will address those concerns to the contractor for correction or resolution. If issues cannot be resolved, the HRPO has the authority to disapprove the research until there is HRPO approval or concurrence. Per reference (r) in the event of a disagreement regarding the Contractor's furnished exemption determination, the HRPO retains final judgment on what research activities or classes of research are covered or are exempt under the contract.
9) Document the review and maintain records of determinations. Ensure records are available for site inspections and assist visits.
10) Notify the Contracting Officer of all HSR determinations.

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7 Principal Investigator Roles, Responsibilities, and Process Guidance

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The PI has primary responsibility for compliance with all human subjects protection regulations, directives, and instructions. PIs for Marine Corps conducted research must be employees of the U.S. Federal Government; as such, they must be either uniformed service members or federal civilian employees. Contractors are not permitted to serve as PIs. The IRB does not recognize Co-PIs. A single PI must be listed on the protocol submission.

7.1 Guidelines for Investigators

PIs shall:

1) Complete and document initial and continuing research ethics and human subjects protections training.
2) Supervise and assume responsibility for all research conducted under the protocol.
3) Obtain necessary approval(s) (EDO, IRB, IO) prior to conducting or continuing research, and prior to implementing proposed amendments to approved research.
4) Obtain written determination of whether the proposed activity is HSR and, if so, whether the research meets criteria for exemption per reference (b).
5) Ensure that non-exempt human subjects projects have been independently scientifically reviewed prior to submission to the convened IRB for review.
6) Notify the IRB in writing of: UPIRTSOs; serious adverse events; non-compliance with the human subjects protection regulations or IRB requirements; and protocol deviations. If unsure whether an incident or event requires reporting, consult with the IRB Chair.
7) Obtain and document informed consent from research subjects, unless the IRB approves a waiver or alteration of the informed consent process per reference (b), and provide subjects a copy of the IRB approved informed consent document prior to the start of research.
8) If the PI will be temporarily unable to attend to PI responsibilities, notify the organizational IRB vice chair or IRB Chair and make provisions to ensure continuation of research and records and data security during the absence. In certain circumstances, such as extended absence, at the discretion of the IRB Chair, the IRB may require that the PI designate a member of the research team to be the Acting PI in their absence. In accordance with Chapter 24, in exceptional circumstances, the PI or PI's organization also may request a temporary administrative hold on the protocol. 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.
9) Any verbal or telephonic communications to the IRB Chair or IRB Administrator regarding the protocol must be followed up with an e-mail or other written

communication for the record.

10) If the PI's employment or primary duties change in any way that impacts their assignment as the PI for research, it is the PI's responsibility to ensure that a proper turnover is done. The PI must submit an amendment to assign a new PI or submit a project Final Report. This action should be done at least 20 business days prior to the PI's departure to ensure a proper turnover.

11) Retain records in accordance with Chapter 25 and Appendix I to verify compliance with reference (b).

12) Ensure that all human subjects used are properly qualified, informed, briefed, and prepared prior to exposure to research risk.

13) Ensure that all associate investigators are covered by a DoD or Federal Assurance and are educated in all phases of research in which they may be involved, including the recruitment of subjects, obtaining informed consent, providing necessary reports, protecting data and other sensitive information, and maintaining required records.

14) Ensure all associate investigators complete and document initial and continuing research ethics and human subjects protections training.

15) Suspend or terminate exposure of human subjects to research-related risks whenever indicated to protect the subject.

16) Obtain institutional approval prior to implementing amendments to the previously approved research project.

    a. PIs shall implement changes to protocols without approval only when necessary to eliminate apparent immediate hazards to the subject. In such cases, the PI shall notify the IRB Chair of the change immediately via telephone or email and shall submit an amendment addressing the change within a timeframe established by the IRB Chair.

17) Submit required Progress Reports or Continuing Review Reports to the IRB in accordance with the schedule established by the IRB.

18) Upon completion of the approved research project, submit a Final Report stating completion status.

19) Obtain written support / non-support of a protocol from the local Marine Corps command(s) where the protocol is to be conducted and/or from which subjects will be recruited before starting research activities.

    a. The local Commander's support for the protocol must be obtained or endorsed at the Lieutenant Colonel (O-5) or Colonel (O-6) level and must be signed by the actual Commander, not "by direction." Local command support / non-support of a protocol does not constitute Marine Corps institutional approval / disapproval of the protocol.

    b. A formal letter is the preferred method of documenting command support. However, the IRB can accept an email from the Commander based on the command's preference.

c. For protocols where individual subjects will be recruited based on specific characteristics (e.g., MOS, assignment experiences, etc.) from a broad range of commands, it may be appropriate to request a letter of support at the general officer or SES level. PIs should consult with their IRB vice chair or the IRB Administrator or Chair regarding this option.

Additional guidance for projects using USMC data is provided in Appendix J.

7.2 Process Guidance

The following section is provided to give a brief overview of the entire review process and provide a quick reference for PIs to find applicable chapters, sections, and forms.

7.2.1 Human Subjects Research Applicability Review

In order to determine if a specific project meets the definition of HSR (as defined in 32 CFR 219), the PI shall submit and Applicability Review Worksheet/Study Information Sheet, along with any supporting documents (e.g., proposed survey, focus group questions) to the IRB Administrator at USMC_HRPP.fct@usmc.mil or their organization's IRB vice chair to initiate an applicability review. For details, see section 9.1 (Determination of Human Subjects Research).

7.2.2 Higher-Level and Other Review Considerations for Project Design

Whether or not a project is determined to be human subjects research, specific elements of research design can affect whether or not higher level reviews are required. If these reviews are required, PIs will need to budget additional time to navigate them. The requirements and timelines for these reviews are not within the USMC IRB's control. PIs are encouraged to reach out to their organizational vice chair or to the IRB early in the design phase to discuss what other review requirements may be triggered by the expected research design. This is particularly important for projects that will involve controversial topics or any of the following categories of subjects:

- U.S. citizens who are:
    - military or civilian personnel from DoD services other than the USMC
    - personnel from other federal agencies
    - not affiliated with the federal government including
        - contractors
        - retirees/veterans
        - other members of the public
- Citizens of other countries who will participate in research activities while located:
    - in their country of citizenship
    - in U.S. locations
    - in non-U.S. location other than their country of citizenship.

Some projects also may be subject to review requirements outside of human subjects research policies, such as safety reviews or USMC Survey Program reviews. The USMC IRB and organizational vice chairs may be able to advise PIs on these requirements during research design. However, it is the PI's responsibility to ensure the protocol has addressed all

requirements prior to starting research activities.

7.2.3 Initial Protocol Submission

NOTE: Submission requirements and processes may vary somewhat across organizations. The information below is for protocols submitted directly from the PI to the USMC IRB. PIs in organizations with an IRB vice chair or EDO should consult with the vice chair or EDO regarding organization-specific processes.

If a project is determined to meet the definition of HSR as required in Paragraph 5.2.1, the PI shall prepare protocols that fully describe the proposed research. To do so, the PI shall submit an IRB Action Request, Full Protocol, Study Personnel Information, Conflict of Interest, and Affirmation Worksheet, Scientific Review, and other supporting documentation as outlined in Chapter 12.

Protocols must be submitted no later than 10 business days prior to scheduled IRB meetings to allow sufficient time for review, in case the protocol requires review by the convened board. Protocols that are greater than minimal risk or that are minimal risk, but do not meet the criteria for exemption or expedited review in Appendices A and B, require convened IRB review. PIs should consult with the IRB Chair or Administrator for the current calendar of scheduled IRB meetings.

Protocols that do not meet this submission deadline will be reviewed at the following month's IRB meeting. If the PI requires consideration / review of the protocol and is not able to submit the package 10 business days in advance of the scheduled IRB meeting, the PI must request an exception to the submission deadline and provide justification for that request. Appropriate criteria might include logistical considerations (e.g., subject pool availability, researcher availability) and time sensitivity of the topic for the intended users, coupled with some evidence that the PI could not reasonably have been expected to submit at an earlier date. The IRB Chair shall notify the PI if an exception will be approved to present the protocol to the IRB for consideration with less than 10 business days' notice. The convened IRB may still determine that they have not had sufficient time to consider the protocol action and may defer or table the consideration until the next scheduled convened board meeting.

The IRB Action Request serves as a declaration of accuracy and completeness. The PI's supervisor's signature indicates that the department/office can support the PI to comply with all regulations and that project has been reviewed for scientific or scholarly soundness. The supervisor shall not conduct the scientific or scholarly review, but shall indicate, by their signature, that the scientific review was conducted. Scientific or scholarly soundness shall be based on a complete scientific or scholarly review of the protocol per the Marine Corps scientific or scholarly review guidance contained in Chapter 19 of this Policy and Procedure. During the applicability review process, an EDO or IRB Chair may note that a full protocol for the project is likely to meet one of the criteria for exemption indicated in Appendix A and communicate to the PI that formal documentation of scientific review, other than supervisor signature, is not required for the initial submission.

The PI shall submit the protocol, with all supporting documentation, to the IRB Administrator. See Chapter 12 for review details. Additional requirements for greater than minimal risk protocols are found in Chapter 13.

7.2.4 Protocol Modification

For modifications to approved research protocols, the PI shall submit an IRB Action Request and other supporting documentation indicating changes requested. If the PI is unsure of whether the changes require submission of an amendment, the IRB administrator, chair, or vice-chair should be consulted. If the protocol is greater than minimal risk or the modification will require convened IRB review, the submission timeline (and requirement to request an exception if the timeline cannot be met) outlined in paragraph 7.2.3, applies. The PI must obtain IRB approval prior to implementing proposed modifications to the approved research protocol. In general, the PI is only authorized to make stylistic changes (e.g., font type, formatting) to an approved protocol. Changes to approved members of the research team, protocol language, process, technique, procedure, population etc., must be reviewed by the IRB.

7.2.5 Continuing Review or Progress Reports

PIs of protocols that have been determined to be greater than minimal risk will be required to submit a request for Continuing Review (CR) at least annually. The IRB may require more frequent CRs at the time of initial review or later in the protocol's lifecycle. The due dates for these submissions shall be set by the IRB Chair at the time the protocol or other protocol action is approved.

PIs of protocols that have been determined to be minimal risk will be required to submit a Progress Report (PR) at least annually. The IRB may require more frequent PRs at the time of initial review or later in the protocol's lifecycle. The due dates for these submissions shall be set by the IRB Chair at the time the protocol or other protocol action is approved. In unusual cases, the IRB may require CRs for minimal risk protocols.

PIs of protocols that have been determined to meet the criteria for exemption may be required to submit a CR or PR annually or on another cycle established by the EDO, IRB Chair, or IRB. These requirements are detailed in Chapter 14.

When a CR or PR is submitted, the PI shall submit an IRB Action Request, a Continuing Review / Progress Report, and any supporting documentation (latest informed consent document, copies of Unanticipated Problem/Adverse Event Reports). See Chapters 12 and 16 for more information.

7.2.6 Final Report

Upon completion of a research project, the PI shall submit an IRB Action Request with a project Final Report, and attach electronic copies of any published book, book chapter, journal article, technical report, or technical notes about the project. Additionally, any presentations or briefs should also be submitted as part of the Final Report.

The HRPP is aware that, especially with scholarly research, production of research outcomes may continue for months or years after data collection is complete and contact with subjects has ceased. In such cases, the PI should indicate in the report that further research outcomes are planned and that copies will be provided to the HRPP when available. It is the PI's responsibility to ensure that copies of research outcomes are provided when available and in accordance with applicable release guidelines and/or copyright guidelines.

7.2.7 Unanticipated Problems, UPIRTSOs and Serious Adverse Events

In the event of an unanticipated problem (protocol deviation, adverse event, UPIRTSO) or serious adverse event, the PI shall submit an IRB Action Request, Unanticipated Problem

Adverse Event Report, and any other supporting documentation.

1) Serious adverse events are to be reported (at least verbally or via e-mail) to the supervisor and IRB Chair or vice chair immediately. The PI shall follow up with a written Unanticipated Problem or Serious Adverse Event Report within 24 hours of discovery of event. See Chapter 20 for additional information.
2) Written reports of unanticipated problems shall be submitted to the Chair or vice chair via the IRB Administrator within 10 business days. See Chapter 20 for additional information.
3) Summaries of unanticipated problem or serious adverse event experiences shall be submitted with each Continuing Review Report and the Final Report for the protocol.

7.2.8 PI Recourse for Disapproved Protocols

If a protocol is disapproved, the PI may revise and submit a new protocol for consideration. PIs revising a disapproved protocol are encouraged to consult with their organization's IRB vice chair or the IRB Chair to ensure the revisions appropriately address the IRB's concerns.

The PI also may make a request to the IRB Chair to attend the next convened IRB meeting and appeal the decision to the board. The IRB Chair shall accommodate such requests to the maximum extent possible. Notification of delays in accommodating such requests or denials must be made in writing within 10 business days of receipt of the request with copies provided to the IO and the PI's supervisor.

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8 Education and Training

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Per references (d), (e), (t), all personnel who conduct, review, approve, support, manage, or oversee DON supported HSR are required to complete initial and continuing research ethics training appropriate to their roles and responsibilities. This includes the IO, all IRB members, EDO(s), HRPO(s), all PIs, ombudspersons, associate investigators, and support personnel directly involved in research. This also includes personnel selected by a commanding officer to serve as local Marine Corps command advisors to research teams. Personnel shall complete their required training before assuming their DON human research protection duties.

Required training shall be repeated/refreshed at least every three years. The IRB Administrator is the HRPP training POC and shall maintain a record of all required HRPP training certificates. For those commands / organizations with their own Institutional Assurance, the HRP Point of Contact at that institution shall ensure that individuals with a role in HSR complete the appropriate training and provide a copy of the completion certificate to the IRB Administrator.

As of the date of this policy, the basic training requirements for personnel who conduct, review, approve, support, manage, and oversee DON supported HSR are met via the role-appropriate course(s) delivered through the CITI Program, which are available to all DON personnel and supporting contractors. The USMC HRPP may, but is not required to, consider alternative training to fulfill education and training requirements if equivalency to a required CITI Program course can be established. The USMC HRPP may require additional academic and/or experiential qualifications appropriate to specific roles or projects.

The USMC IRB shall provide additional continuing education opportunities to IRB members and HRPP staff at least once annually. These educational opportunities may focus on traditional IRB-related matters, developing knowledge of topics of special interest to the service, or other issues as determined by the IRB Chair and USMC IO.

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9 IRB Membership Requirements

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The role of the USMC IRB is to ensure the safety and welfare of human subjects in research. The IRB is charged with ensuring compliance with mandated policies and procedures through the application of sound judgment regarding the relative benefits versus risks associated with each specific research effort.

9.1 General Overview

The IRB coordinates all activities related to the protection of human subjects, ensuring that proper procedures are in place for safe conduct of research through a review of documents and research monitoring. The IRB is charged with ensuring compliance with mandated policies and procedures through the application of sound judgment regarding the relative benefits versus risks associated with each specific research effort.

9.2 Composition of the IRB

The IRB members must be current federal employees (military or civilian) or individuals appointed under the Intergovernmental Personnel Act (IPA). The IRB shall have at least five members, of varying backgrounds in accordance with reference (b), in order to promote complete and adequate review of varied research activities, and shall be sufficiently qualified through experience and expertise to fulfill their obligations.

1) The voting members of the IRB shall consist of personnel either from the Marine Corps or external board members through agreement with their organization(s). The IO may appoint additional voting members to meet requirements. (See Appendix K)
2) Alternate members of the IRB may be appointed by the IO to share the responsibilities of IRB membership with a primary voting member. Attendance of alternate members may be requested by the IRB Chair or Administrator for convened IRB meetings to establish a quorum for voting. (See Appendix K)
3) The IRB shall not consist entirely of men or women.
4) The IRB shall not consist entirely of members of one profession.
5) The IRB shall include at least one member from a scientific area and at least one from a non-scientific area.
6) The IRB shall include at least one member who is not otherwise affiliated with the Marine Corps and who is not an immediate family member of a person who is affiliated with the Marine Corps.
7) The IRB Chair is designated in writing by the IO. The Chair shall be appointed for a one-year term. Unless a different appointment is made by the IO, the term shall be automatically renewed. Initial appointments and automatic renewals do not require a vote of the IRB. Once appointed by the IO, the Chair may only be involuntarily removed by a majority vote at a convened meeting of the IRB. In cases where the Chair voluntarily leaves the position or is permanently unable to serve in the position due to employment status or for personal reasons, no vote is required. (See Appendix K)

8) The IRB Chair or a vice chair may serve as the administrator for the IRB.

9) All IRB members must be free of any conflict of interest (COI) with any protocol that they review. IRB members are required to recuse themselves from IRB discussions and / or voting when any known COI exists. See section 1.14 Conflict of Interest for more information on this topic.

10) The IO shall not be a member of the IRB.

11) Members shall serve a two-year term. They may serve consecutive terms, with no term limit. Unless a different appointment is made by the IO, the term shall be automatically renewed.

12) The board may include alternate members (alternates).

    a. Alternates may be paired with a primary member based on organizational affiliation or be appointed to serve as an alternate based on category (scientist/non-scientist, sex, affiliation, etc.) and/or subject matter expertise (e.g., physical sciences, biomedical sciences, social and behavioral sciences, special topical expertise, etc.). For example, an unpaired alternate may be appointed who can substitute for any scientist on the board or for any member with expertise in the physical sciences. Paired alternates also may substitute based on category or subject matter expertise if specified in their appointment or appointment-related documentation. For example, an alternate paired with a member from Marine Corps University might also substitute for other scientist members or members with expertise in program evaluation. The terms of the appointment shall include an explanation of allowed alternate roles.

    b. Alternates may attend any meeting for informational purposes and will be included on all routine IRB correspondence. However, alternates shall not be counted toward quorum and shall not vote unless acknowledged by the Chair as serving in their alternate capacity for the meeting.

    c. Alternates paired with vice chairs shall not perform vice chair duties unless specifically appointed as an alternate vice chair.

13) Consultants may be used if a specific subject matter expertise relating to proposed research is required by the Board (e.g., an exercise physiologist may be used in research related to physical fitness). These individuals may be excluded from deliberations and shall neither vote nor be counted when determining the presence of a quorum.

14) If classified research is reviewed, each reviewing IRB member must hold an appropriate security clearance and have been granted access.

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10 IRB Functions and Operations

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10.1 General Overview

The primary role of the USMC IRB is to ensure the safety and welfare of human research subjects. The USMC IRB reviews and approves or disapproves research protocols and amendments and reports associated with approved protocols. It also coordinates with the Marine Corps IO or other IOs supported by IAIRs to ensure they have an appropriate opportunity to review and approve or disapprove research.

The USMC IRB's main focus is review and oversight of human subjects research conducted by Marine Corps personnel or military and government civilian employees assigned to the Marine Corps, including projects conducted by other Marine Corps organizations holding an institutional assurance that have established agreements for IRB services with the USMC HRPP.

At the discretion of the Marine Corps IO and IRB Chair, the USMC IRB may enter into agreements to review projects for other government and non-government researchers. Whether or not to enter into such an agreement is entirely at the discretion of the IRB Chair and Marine Corps IO and may be based on current IRB workload, available expertise related to the research topic, or other factors. Note that requests to provide IRB services for contractor-led projects must be made by a DoD organization, not by the contracting vendor.

The IRB coordinates all activities related to the protection of human subjects, ensuring that proper procedures are in place for safe conduct of research through a review of documents, inspections, and observation. Sufficient dialogue between the PI and IRB members, and among IRB members, should occur to provide the board with sufficient understanding of the research so that they can properly appreciate the risks and benefits involved.

1) The IRB shall ensure that, in every project or task in which human subjects are involved:
    a. The rights and welfare of the subjects are adequately protected.
    b. The risks to subjects are outweighed by the potential benefits and by the importance of the knowledge to be gained.
    c. Informed consent of the subjects is obtained by methods that are adequate and appropriate as required by reference (b) unless waived in accordance with reference (b).
    d. The applicability of this policy to any research proposal involving human subjects is determined.
    e. The level of risk involved is determined based on the definitions in reference (b) and (d), and sound professional judgment.
2) A quorum is required for the IRB to vote or take other actions. A quorum is defined as at least half of the IRB's voting members (excluding alternates, ad hoc members, and consultants) including at least one member who is listed in the official IRB roster as having a non-scientific background. For example, if the IRB has five members, at least three members, including one non-scientist must be present to make a quorum. Should the quorum

fail during a meeting (i.e., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), the IRB may not take further actions or votes unless the quorum can be restored. The IRB may meet if a quorum cannot be established, but may not vote or take other actions.

3) Approval or disapproval of protocol actions or other matters requires a majority vote of the voting members present at a meeting for which a quorum has been established. For example, if six voting members are in attendance, four votes are required to establish a majority.
4) When both the primary and alternate IRB members are present at a meeting, both may be counted toward quorum if necessary. If necessary, the IRB Chair may designate the alternate member as a voting member for the entire meeting or specific actions. If not needed for the quorum, alternate members may not vote if the primary member is present.
5) The votes of individual members shall not be recorded by name, but only as an anonymous total: For, Against, or Abstaining.
6) Any member who disagrees with the majority opinion of the board may attach an anonymous opinion to the meeting minutes and, when applicable, to the materials sent for IO approval.
7) Except when an expedited review procedure is used, all non-exempt protocol submissions shall be reviewed at convened meetings at which a quorum is established.
8) The convened IRB shall meet and conduct reviews for all projects identified by the IRB Chair as involving either greater than minimal risk or minimal risk but determined to not meet criteria for exemption or expedited review.
9) The convened IRB shall meet quarterly or as needed. A meeting may be conducted outside regularly scheduled times at the request of the IO, IRB Chair, or IRB member.
10) The IRB shall conduct reviews in accordance with procedures outlined in Chapter 11.
11) For non-exempt research at all levels of risk, the IRB shall conduct the review in accordance with applicable guidance and forward written approvals or disapprovals to the IO for review.
12) If the level of research risk is determined to be greater than minimal risk, the IRB shall also ensure that the specific additional requirements listed in Chapter 13 are met.
13) The IRB Chair, IRB Administrator, or vice chair shall notify the PIs of the IO's actions or recommendations.
14) The IRB shall determine which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review. The IRB shall conduct continuing oversight of all approved research via continuing reviews and progress reports as described in Chapter 18 and through monitoring activities as described in Appendix E.
15) The IRB shall maintain adequate documentation of its activities permanently, in accordance with and Appendix H.

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11 Project Review Process

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IRB approval and, for non-exempt research, IO permission to implement HSR is required prior to recruiting and enrolling subjects, analyzing data, conducting research interventions, or preparing publications or presentations.

While this chapter focuses on determinations and initial reviews, the review categories and processes also generally apply to amendments and reports submitted for human subjects research.

11.1 Determination of Human Subjects Research

11.1.1 Human Subjects Research Applicability Review Process

The PI coordinates with the IRB Administrator, IRB vice chair, or EDO for a review to determine whether the work meets the definitions of research and/or HSR. Only the IRB Chair, EDO, or, if authorized, a vice chair, can make this determination. An Applicability Review Worksheet shall be submitted for all HSR applicability reviews.

Materials submitted for applicability review must provide sufficient information to enable the reviewer to make an informed determination as to whether the study meets the definitions of HSR. This will normally include who is sponsoring the study, who is conducting the study, the purpose of the study or data collection, what the study with involve, the intended subjects or participants, with whom the results of the study will be shared, and draft data collection instruments or sample questions.

11.1.2 Human Subjects Research Determination Authority

The IRB Chair or EDO may make the determination that the work meets the definition of HSR. The IRB Chair also may defer to an authorized IRB vice chair. If a determination of "not HSR" is made, the IRB Chair, EDO, IRB Administrator, or authorized vice chair sends documentation, via e-mail or other written notification, to the PI documenting the decision. Documentation of determinations made by vice chairs or by an EDO outside the USMC HRPP must be submitted to the IRB Administrator for record-keeping. Projects that are determined to meet the definition of HSR must then submit a full protocol to the IRB Administrator. Note that organizations with vice chairs or EDOs may require that submissions be made through those individuals rather than directly to the USMC IRB. The PI should consult local organizational guidance.

11.2 Protocol Package Submission

If the project is determined to meet the definition of HSR, the PI must submit a protocol package. When the protocol originates within a command or organization that has its own Institutional Assurance, or which has a vice chair appointed to the IRB, the protocol shall be submitted via the vice chair or HRP Point of Contact. If no vice chair or Point of Contact is available, the materials may be submitted directly to the IRB Administrator. Protocol requirements are found in Chapter 12.

The IRB Administrator receives protocol packages, checks the packages for completeness, assigns a protocol number, and keeps the protocol packages and supporting documentation on file for the IRB. The IRB Administrator tracks research protocols through the review process and

throughout the lifecycle of the protocol.

11.3 Protocol Review

The IRB Chair and, in submissions from organizations with vice chairs, at least one vice chair conduct preliminary reviews of protocol submissions as indicated below. The vice chair shall review and provide their initial recommendation to the IRB Chair for review and concurrence. The vice chair should comment on the level of risk and whether it meets a specific criteria for exemption or expedited review.

During initial review, the IRB Chair shall consider whether the protocol may require higher-level reviews in accordance with reference (e). If higher level review may be required, the IRB Chair shall advise the PI regarding requirements and provide any available information regarding review timelines.

11.3.1 Exemption

Protocols that are of minimal risk and meet one of the criteria for exemption as outlined in Chapter 14 may be exempted from some specific IRB requirements, including the requirement to hold a valid assurance, obtain scientific review, review by a full IRB, and approval from an IO. The protocol may also be exempted from the requirement for maintaining signed documentation of informed consent. Exemption determinations must be made by an Exemption Determination Official (EDO) appointed by an IO. Exemption determinations made by EDOs outside the USMC HRPP must be sent to the USMC IRB Chair to ensure exempt protocols are appropriately integrated in the USMC IRB processes and records as detailed in Chapter 14. If exempt, the IRB Chair, EDO, or IRB Administrator shall send the approval determination to the PI and shall notify the IO of the exempt determination through the submission of IRB minutes or other written notification.

11.3.2 Minimal Risk–Expedited Review

Protocols that are of minimal risk and meet one of the categories for expedited review as outlined in Chapter 11 may be, but do not have to be, approved under expedited review procedures. The IRB Chair may conduct an expedited review alone or may seek a vice chair recommendation. The IRB Chair also may determine that, despite eligibility for expedited review, protocol complexity or other factors make it more appropriate for review to be conducted by the convened IRB. After completion of IRB-related approvals, all non-exempt minimal risk protocols are sent to the USMC IO for approval.

11.3.2.1 Delegation of Expedited Review Authority for Minimal Risk Protocols

The USMC IRB does not routinely delegate authority for expedited reviews beyond the IRB Chair. In unusual circumstances, such as the extended absence of the IRB Chair, the IRB Chair or IO may delegate authority to conduct expedited reviews for minimal risk protocols to an experienced vice chair.

11.3.3 Minimal Risk–Convened IRB Review

Protocols that are of minimal risk but do not clearly meet the requirements for exemption or expedited review (or for which the IRB Chair determines that convened IRB review is appropriate as indicated above) shall be sent to the convened IRB for review. If the IRB Chair

and vice chair are not in agreement based on their preliminary review and do not reach a consensus, the protocol shall be submitted to the convened IRB for review. After completion of IRB-related approvals, all non-exempt minimal risk protocols are sent to the USMC IO for review and approval or disapproval.

11.3.4 Greater Than Minimal Risk

Protocols that are determined to involve greater than minimal risk by the IRB Chair and a vice chair shall be submitted to the convened IRB for review. If the IRB Chair and vice chair come to a different conclusion regarding the level of risk, the protocol shall be submitted to the convened IRB for the determination. After completion of IRB-related approvals, all greater than minimal risk protocols are sent to the USMC IO for review and approval or disapproval.

11.3.4.1 Expedited Review of Changes to Greater Than Minimal Risk Protocols

In accordance with reference (b), certain changes to greater than minimal risk protocols may be conducted using expedited procedures. Examples of changes that can be reviewed using expedited procedures include personnel changes (other than PI changes) and minor or administrative changes to the protocol, recruiting materials, informed consent documents, photographic/video release documents, data collection instruments, and other materials associated with the protocol. Expedited review procedures may not be used if the change involves an increase or change to subjects' risks except when the change is to reduce risks and expedited review is in the best interest of subjects. Expedited review procedures may not be used if the change involves a change to subjects' rights except when expedited review is in the best interest of subjects.

11.3.4.2 Delegation of Expedited Review Authority for Changes Greater Than Minimal Risk Protocols

The USMC IRB does not routinely delegate authority for expedited reviews beyond the IRB Chair. In unusual circumstances, such as the extended absence of the IRB Chair, the IRB Chair or IO may delegate authority to conduct expedited reviews of changes to greater than minimal risk protocols (as limited in this chapter) to an experienced vice chair.

11.3.5 Review of Approved Actions

All protocol reviews completed by the IRB Chair, and EDO, or a vice chair are provided to the convened IRB prior to the next scheduled meeting. Any IRB member, during or outside of an IRB meeting, may raise questions or concerns about a protocol or about review actions taken. If a member's concerns could lead to altering or placing contingencies on an approval, the IRB Chair shall consult with at least one additional vice chair and decide to either communicate the changes or contingencies to the PI or refer the matter for discussion and vote at the next convened IRB meeting. If a member wishes to ask questions of or request clarifications from a PI, the IRB Chair, EDO, or vice chair shall transmit the questions to the PI and the PI's response to the IRB member.

11.4 Convened IRB Review

When all preliminary requirements have been met, the convened IRB meets to consider research protocol packages (and other matters). The IRB Chair, IRB Administrator, or organizational vice chair shall notify the PI if changes are required prior to approval within 10 business days after

the convened IRB meeting.

If the IRB Chair expects that IRB may have substantive or technical questions regarding a protocol, the Chair or IRB Administrator will invite the PI to attend the appropriate section of the IRB meeting.

During the meeting the convened IRB shall:

1) Review each research protocol scheduled for discussion and vote, confirming the assigned level of risk.
2) Determine if (a) 32 CFR 219.111, (b) DoD-DON requirements, and (c) other state, federal, or international requirements related to HSR are met.
3) If applicable, ask a PI to discuss the procedures to be performed or to answer questions if additional information is needed to achieve sufficient understanding of the research.
4) Approve or disapprove all protocol actions using appropriate guidelines. The IRB may:
    d. Approve as submitted.
    e. Require modifications in order to secure approval. In this case the IRB may approve pending review or verification of minor IRB-required modifications by the IRB Chair or convened IRB. Protocols found by the IRB to require significant modifications must be brought back before the convened IRB for review or verification.
    f. Disapprove the protocol or associated amendment or report. The IRB shall clearly describe the reasons for disapproval. The IO is prohibited from approving a protocol the IRB has disapproved.
    g. Refer the review to a DoD IRB in place at an institution or organization where the research is to be executed.
    h. Require that a PI submit more than annual continuing review or progress reports.
    i. Require that a project have third parties observe research or consent processes. For greater than minimal risk research (or minimal risk research in which the IRB deems it necessary) the IRB shall identify and approve a named ombudsperson, or approve an ombudsperson identified by the PI, for research involving military members or federal employees of the DoD, when recruitment occurs in a group setting. The ombudsperson shall not be associated in any way with the research. The ombudsperson shall be present during the recruitment in order to monitor that the voluntary involvement or recruitment of the military members or DoD employees is clearly and adequately stressed and that the information provided about the research is clear, adequate and accurate.
    j. If the convened IRB determines that changes to the protocol are necessary, the IRB Administrator or IRB Chair shall notify the PI within 10 business days of the meeting.

11.5 Verification from Sources Other Than Investigator

In accordance with reference (b), when reviewing amendments or reports for some protocols, the IRB Chair or IRB may determine that it is necessary to obtain verification from a source other

than the investigator that no changes have occurred since the last IRB review. This verification may be required based on a range of factors, such as concerns or allegations raised regarding the research, the experience of the PI, or the specific risks associated with the protocol. Verification may be obtained through post-approval monitoring activities or discussions with individuals knowledgeable about the research. If such verification is sought, the IRB Chair and IRB Administrator shall document the rationale, verification process, and outcomes in the protocol's records and provide a copy to the PI within 10 business days of either completion of the verification report or of the date minutes were issued for the meeting in which the verification was discussed.

11.6 IO Package Review (Non-Exempt Research)

When the research protocols have been reviewed and voted on by the convened IRB, or the Chair, alone or with vice chair concurrence, in the case of expedited reviews, a review package is assembled and forwarded to the IO. (Note: As allowed by reference (e), IO review may take place before or after IRB review. In general practice, IO review will take place after IRB review, but the IRB Chair may make exceptions to this practice to facilitate an efficient review process.)

The packages include:

1) The minutes of the IRB meeting (if applicable).
2) The IRB assessment of the risk level, which must be either minimal risk or greater than minimal risk.
3) The IRB's approval or disapproval.
4) The assignment and responsibilities of the ombudsperson when required.
5) The anonymous dissenting opinion(s) of board member(s), if any.
6) The final research protocol, informed consent form, and all supporting documentation.
7) Copies of or documentation of approved IIAs, IAIRs and other research agreements (if applicable).

The IRB Chair, IRB Administrator or vice chair shall provide the PI with copies of the IRB's and IO's actions on the research protocol within 10 business days of receiving the completed IO package.

11.7 IO Review and Approval

The IO may take one of the following actions, based on the criteria established in reference (e):

1) Approve the protocol,
2) Require additional safeguards or modifications,
3) Forward the review package to a higher reviewing authority, or
4) Disapprove the protocol.

Within the USMC institutional assurance, IO review typically takes place after the protocol has been approved by expedited procedures or the convened IRB. IO review may take place before review by the IRB Chair or IRB. However, if the IRB disapproves a protocol after IO permission

for implementation, the IO's permission is nullified and the research may not be conducted. Under no circumstances may the IO give permission for implementation of a protocol that the IRB has disapproved.

In the case of IRB disapproval of research, the IO may recommend the PI revise the protocol and re-submit to the IRB. In the case of the IO not giving permission for implementation of the research, the IO may recommend the PI revise the protocol and re-submit to the IRB.

When a protocol receives has been approved by both the IRB and the IO, the IRB Chair issues an approval to the PI with an expiration/renewal date if applicable. Only thereafter may recruitment and research begin.

11.8 DON HRPP Review

The IRB Administrator or Chair forwards all completed protocol actions and supporting documentation and, if applicable, the IO's approval or disapproval to DON HRPP for Department of the Navy Headquarters (HQ) level review. For protocols reviewed by the USMC IRB on behalf of an institution supported through an IAIR or other research agreement, the IRB Chair shall forward a copy of the IO's approval and all protocol documentation to the Institution's appointed vice chair or HRP Point of Contact.

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12 IRB Protocol Submission Package for Human Subjects Research

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The research protocol for HSR, whether needing convened IRB review, expedited review, or exemption determination shall be submitted to the IRB Administrator, and, at a minimum, shall include all the elements found in the Full Protocol Template.

The protocol shall be submitted with:

1) An IRB Action Request with supervisor signature.
2) A copy of the informed consent document and/or script, if required.
3) A signed Personnel Data, Investigator Affirmation, and Conflict of Interest worksheet covering all investigators (PI and associate investigators) and other project personnel who will have contact with subjects or work with subjects' information or data.
4) Training and qualifications documentation for the PI and for all investigators to include CITI training and, if applicable, project specific training. Documentation of qualifications of research personnel may be provided using resumes, curriculum vitae, biographical sketches, or similar materials.
5) An independent scientific or scholarly review for all non-exempt research. (See Scientific/Scholarly Review Worksheet)
6) Local Marine Corps command letter(s) of support / non-support of protocol. Support must be obtained at the O-5 or O-6 level for each command where research activities will be conducted or from which subjects will be recruited and must be provided by the actual CO, not "by direction." At the discretion of the IRB Chair, based on the specific details of the protocol, the following alternatives to formal letters of support may be allowed:
    a. Emails from COs of involved units.
    b. A flag officer-level letter of support for projects involving a broad range of commands (e.g., a service-wide survey).
7) Installation or facility approval. Reference (d) requires that DoD researchers obtain approval from the command or component responsible for the facility where the research will take place. In some cases, the USMC IRB may be able to accept the letter of support from the local commander as covering this requirement. However, in cases where recruitment or other research activities may take place across commands at an installation, a letter from the installation commander may be required. PIs should consult with their organizational vice chair or the IRB to determine requirements.
8) Individual Investigator Agreement(s) (IIA) for any member(s) of the research team not covered under the Marine Corps assurance.
9) Institutional Agreement for IRB Review (IAIR) when collaborating with an institution or investigators that are covered by a separate DoD or Federal Assurance.

For protocols determined to be greater than minimal risk, additional requirements are found in Chapter 13.

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13 Greater Than Minimal Risk

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Due to the increased possibility of injury (whether physical, psychological, financial, social, or other) arising from participation in greater than minimal risk HSR, every protocol involving greater than minimal risk shall include an arrangement for emergency treatment (or resources as appropriate) and necessary follow-up of any research-related injury or harm.

1) An appropriate emergency treatment plan shall be developed and necessary personnel training completed, before exposure of the subject to the research risk. Sufficient supplies and equipment shall be available to administer immediate care and stabilize the subject for transport to an appropriate medical facility, if appropriate, or triage other harms as they might occur. Arrangements shall be made in advance for timely emergency transport from the site of the research to a competent medical facility in the event of need.
2) In accordance with references (b) and (d) the protocol and consent documents shall include an explanation regarding whether any compensation and any medical treatments are available for research–related injuries. This explanation shall include all information as required under reference (d).
3) Research ombudsperson(s) must be assigned to the project by the IRB. In addition to the basic qualifications listed in Paragraph 3, the ideal research ombudsperson will have experience with HSR and the particular type of research being monitored.
4) The ombudsperson(s) must meet the criteria set out in reference (d). Specifically, they
    a. Must not have a conflict of interest with the research or be a member of the research team.
    b. Must be present during the HSR recruitment, monitoring that the recruitment and informed consent explain that participation is voluntary and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials.
    c. Should be available to address DoD-affiliated personnel's concerns about participation.
5) If the research is biomedical in nature, a research ombudsperson or at least one member of the research team or biomedical support staff shall be in close proximity to the research subject at all times during research related activities. This person shall have at least current basic life support (BLS) training, familiarity with any special equipment or clothing worn by the subject, and have a means to immediately summon assistance.
6) In all research involving significant physiological stress to the research subject, specific parameters shall be included in the research protocol clearly specifying the criteria both for cessation of the subject's exposure to the stress and for their elimination or disqualification from the project.
7) For research in which the primary risks to participants are not physical or psychological, but rather social, financial, or other, the PI and IRB Chair will coordinate to develop an appropriate set of duties for the ombudsperson(s).

8) For research involving greater than minimal risk and also involving military personnel, it is imperative that unit officers and noncommissioned officers (NCOs) do not influence the decisions of their subordinates to participate or not to participate as research subjects as required in reference (d). Unit officers and senior NCOs in the chain of command shall not be present at the time of research subject solicitation and consent during any research recruitment sessions in which members of units under their command are afforded the opportunity to participate as research subjects. When applicable, officers and NCOs so excluded shall be afforded the opportunity to participate as research subjects in one or more separate recruitment sessions. During recruitment briefings to a unit where a percentage of the unit is being recruited to participate as a group, an ombudsperson not connected in any way with the proposed research or the unit shall be present to monitor that the voluntary nature of individual participants is adequately stressed and that the information provided about the research is adequate and accurate.

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14 Research That Meets Criteria for Exemption

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All HSR activities under Marine Corps jurisdiction shall be reviewed to determine whether the research meets one or more of the exemption categories described in reference (b). The IRB may not create new categories of exempt research. Only an Exemption Determination Official (EDO) designated under a Marine Corps organization's institutional assurance may determine which activities meet one of the categories as exempt research and may take the actions described in this chapter. See Appendix A for a listing of the categories of exemption.

14.1 EDO Role and IRB Oversight

The IRB retains oversight of exempt research. EDOs may determine that a research protocol is exempt, conduct initial review and approval of exempt research protocols (except those requiring limited IRB review), and approve or acknowledge amendments, changes, and reports associated with approved exempt research. The convened IRB may vote to change the review, approval/acknowledgement process, and reporting requirements for specific protocols.

Except in time-sensitive circumstances, EDOs are expected to consult with another EDO or IRB vice chair during review of initial submissions and amendments involving substantive change.

EDOs primarily will review projects that originate within the parts of the USMC covered by their organization's institutional assurance (IA), but are expected to consult with EDOs in other assured institutions as needed.

When an EDO has been cross appointed in multiple assurances, they may review projects falling under other IAs when requested by another assured institution's EDO, IO, or the IRB Chair in order to facilitate timely review of submissions.

EDOs may review projects (within their own IA or, if cross-appointed and if requested, within other IAs) for which the original determination and initial review were conducted by another EDO in order to facilitate timely review.

14.2 Initial Submission Requirements and Approval Process

NOTE: Submission requirements and processes may vary somewhat across organizations. The information below is for protocols submitted directly from the PI to the USMC HRPP's EDO. PIs in organizations with their own EDOs should consult with their EDO regarding organization-specific processes.

Under reference (b) human subjects research that meets the criteria for exemption is exempt from the provisions of reference (b) except in cases where limited IRB review is required. However, because the USMC has determined that the USMC IRB will provide review and oversight for exempt human subjects research, exempt protocols are subject to the same ethical standards, human subjects protections, and applicable DoD, DON, and Marine Corps policies and procedures as protocols that are determined not to meet the criteria for exemption.

There is no inherent requirement to provide documentation of informed consent or continuing review for exempt human subjects research, but the IRB may require these if deemed appropriate.

Documentation of an independent Scientific or Scholarly Review is not required for exempt

research.

The PI shall submit to their organization's EDO or the IRB Administrator a full protocol package. The package must include at least the following:

- Action Request
- Personnel Data, Investigator Affirmation, and Conflict of Interest Worksheet
- Full Protocol
- Informed consent documents if consent will be documented, study information sheets or scripts if consent will not be documented, or a request for a waiver of the requirement to obtain consent with a justification in accordance with reference (b).
- Data collection instruments or sample questions, if applicable
- For projects involving the use of existing data, a description of data sources and specific data types/categories/fields.

Unless the EDO determines that an exempt protocol falls into a category requiring limited IRB review (see Appendix A), the EDO conducts the initial review and approval or disapproval. If the exempt protocol falls into a category requiring limited IRB review (see Appendix A), the EDO conducts a preliminary review and then transfers the package and a recommendation to the IRB Chair or to a vice chair authorized by the IRB Chair. The IRB Chair or authorized vice chair, in consultation with the EDO, determines if the limited IRB review can be conducted using expedited procedures or requires review by the convened IRB and takes appropriate actions in accordance with Chapter 11 of this policy.

The EDO shall provide to the PI written documentation of the final determination of whether or not a research activity meets criteria for exemption, including citation of the specific category justifying the exemption under reference (b). The EDO also shall provide to the PI written documentation of protocol approval either by the EDO or, if limited IRB review was required, by the IRB Chair, authorized vice chair, or IRB.

14.3 Changes and Required Reports - Submission and Approval Processes

In all cases where a submission is approved or acknowledged by an EDO, the PI shall be informed that the submission will be made available to the IRB prior to the next convened meeting and that board members may raise questions or concerns that the PI will be required to address.

Any proposed changes to a protocol determined to meet criteria for exemption must be submitted as an amendment (except as indicated below) and approved by an EDO or the IRB prior to implementation. Certain proposed changes may disqualify the research from meeting an exemption and require either an expedited or convened IRB review prior to approval.

Personnel changes not involving the PI and minor administrative changes, such as updating contact information or Survey Control Numbers on informed consent documents, shall be submitted using an IRB Action Request and the Personnel Data, Investigator Affirmation, and Conflict of Interest Worksheet. Submissions including adding personnel or changes in personnel roles shall include documentation of training appropriate to the role(s) of the individual(s) involved. Such changes shall be acknowledged in writing by an EDO, but do not require formal approval. Acknowledgement must be received before changes are implemented.

Progress Reports are required at least annually for exempt protocols unless another reporting

cycle is directed by the IRB and shall be submitted using an IRB Action Request and Continuing Review/Progress Report Template. The PI shall submit Progress Reports to the EDO at least 10 business days prior to the due date unless a later submission date is approved the EDO or IRB Chair. The due date for the first Progress Report shall be set by the EDO at the time of the initial approval and communicated in writing to the PI. When an EDO acknowledges a Progress Report, the EDO shall set the due date for the next Progress Report and communicate it in writing to the PI. Progress Reports shall be reviewed and acknowledged in writing by an EDO, but do not require formal approval.

A Final Report is required for exempt protocols when the research is complete and shall be submitted using an IRB Action Request and Final Report Template. The PI shall submit the Final Report to the EDO at least 10 business days prior to the date that was set for the next Progress Report unless a later submission date is approved by the EDO or IRB Chair. Final Reports shall be acknowledged in writing by an EDO, but do not require formal approval.

14.4 Late Progress Reports or Final Reports

EDOs shall report to the IRB any protocol for which a Progress Report or Final Report was not received in a timely manner. The IRB may, but is not required to, consider delinquent reports associated with exempt protocols as evidence of non-compliance.

14.5 Additional Requirements

Because a protocol meets criteria for exemption under the rule does not mean the IRB is under any obligation to determine that the study is exempt from the regulations. The IRB may impose a higher level of protection for subjects but may not approve a lower level of protection than that indicated by the exemption per reference (b).

At any time, based on the details of the protocol, the conduct of research, and/or changes in the research environment, the IRB may vote to require that future actions for an exempt protocol must be approved by the IRB Chair or the convened IRB on a temporary or permanent basis.

14.6 Notification to and Review by the IRB

Approvals and acknowledgements by an EDO other than the IRB Chair shall be forwarded to the IRB Administrator or Chair within 10 business days of the action for record-keeping and addition to the agenda for the next convened IRB meeting.

All exempt research protocols, amendments, report submissions, and changes approved or acknowledged by an EDO shall be made available to the IRB for review prior to the next convened meeting. Members may raise questions or concerns for the PI to address. These shall be communicated to the PI by the approving EDO, IRB Administrator, or IRB Chair and the resolution shall be provided in writing to the IRB via email at the time of resolution and as read-ahead material prior to the next convened meeting. The IRB shall determine at the next convened meeting whether further action is required. The IRB's decision shall be communicated to the PI by the approving EDO, IRB Administrator, or IRB Chair within 10 business days after the decision is made.

14.7 Institutional Official Notification

An EDO may exempt research without referral to the IO. If approved by the EDO, the IO will be provided written notice of the approval of a protocol as meeting criteria for exemption.

Typically, this notification will be accomplished through the IRB Administrator, IRB Chair, and/or appropriate vice chair providing the IRB meeting minutes to the USMC IO and other IOs as appropriate. However, an IO also may be provided with a copy of the exempt protocol or other submission package at the time of approval or acknowledgement based on IO preferences, the EDOs assessment of the significance of the research to the service, or other reasons determined by the EDO, IO, or IRB.

14.8 DON HRPP Notification

The IRB Administrator or IRB Chair shall forward research that meets criteria for exemption to DON HRPP for headquarters level review.

14.9 Changes to the Provisions of this Chapter

Except as prohibited by higher-level guidance, the IRB may vote to change the provisions of this chapter in ways that apply to all exempt research originating in assured institutions relying on the IRB. Changes may include requiring greater or lower levels of reporting and oversight, altering submission requirements, and/or altering approval and acknowledgement authorities and procedures. Any such changes shall be documented in a policy letter signed by the IRB Chair and USMC IO and shall be incorporated in the next update to this policy.

Notification of planned changes shall be provided to all IRB vice chairs and members and to the IOs and HRP POCs of all assured institutions relying on the IRB within 10 business days of the IRB's decision. Copies of the resulting policy letters or policy updates shall be provided to all IRB vice chairs and members and to the IOs and HRP POCs of all assured institutions relying on the IRB within 10 business days of approval of the policy letter or policy update.

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15 Expedited Review Process

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The IRB Chair and, if applicable, vice chair shall determine whether research protocols meet criteria for review under expedited procedures as defined in references (b) and (h).

15.1 Expedited Review Categories

The expedited review process is intended to streamline the review process without any decrease in the level of protection of the human subject.

1) The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
2) The research categories, as found in reference (h) are listed in Appendix B. Categories 1 through 7 pertain to both initial and continuing IRB review.

15.2 Expedited Review Criteria

1) The IRB Chair and, if applicable, vice chair may initiate an expedited review procedure for two specific reasons:
    a. Review of research activities that involve no more than minimal risk and that fall into one or more of the nine categories listed in Appendix B.
    b. Minor changes to research protocols approved within the last year.
2) All research, unless determined to meet the criteria for exemption or expedited review, regardless of the assigned level of risk, must be reviewed by the convened IRB.
3) Under the expedited review process, the reviewer may exercise all the authorities of the IRB, including requiring changes for approval, but the reviewer may not recommend disapproval, which is reserved for the convened IRB.
4) If changes requested under an expedited review are unacceptable to the researcher, they may request review by the convened IRB under regular review procedures.
5) The IO reviews all expedited review protocols and has the same approval and disapproval options as listed in section 11.6.
6) The IO may restrict, temporarily suspend, or choose not to authorize use of the expedited review procedure.
7) The expedited review process may not be used for the following:
    a. Any classified research projects involving human subjects.
    b. Any greater than minimal risk research with the exception of certain protocol actions in greater than minimal risk research as allowed under reference (b).
    c. Where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial

standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections shall be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

d. Any research involving prisoners.

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16 Criteria for Approval of Research

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In order to approve research covered by this policy the IRB shall determine that all the following requirements are satisfied:

1) Risks to subjects are minimized:
    a. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
    b. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3) Selection of subjects is equitable. In making this assessment the IRB should consider the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, military personnel, mentally disabled persons, or economically or educationally disadvantaged persons.
4) Informed consent shall be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by reference (b) unless a waiver is requested and is consistent with reference (b).
5) Informed consent shall be appropriately documented, in accordance with, and to the extent required by reference (b) unless a waiver is requested and is consistent with reference (b).
6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8) When some or all subjects are likely to be vulnerable to coercion or undue influence, such as children, military personnel, DoD civilians, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
9) For greater than minimal risk protocols and non-exempt minimal risk protocols in which there is the potential for physical injury, in accordance with references (b) and (d) the protocol and consent documents shall include an explanation regarding whether any compensation and any medical treatments are available for research–related injuries. This explanation shall include all information as required under reference (d).

10) As appropriate to the protocol, the PI articulates a clear plan for destruction or retention/sharing of data upon project completion. If data will be retained and/or shared, the plan must indicate whether the retained/shared data will be de-identified and the explain the provisions to ensure data will be protected to the same standard in the protocol and, if applicable, informed consent agreement.

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17 Informed Consent

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Voluntary informed consent is fundamental to ethical research involving human subjects. Informed consent is not simply a document; it is a process of ensuring that persons who agree to take part in research are fully informed about the potential risks and benefits from their participation. In long-term and / or multi-context research, consent may be an ongoing process throughout the research. No investigator may involve a human subject or a human subject's data in research covered by this policy and associated procedures except when the subject is a volunteer and the investigator has obtained informed consent from the subject unless a waiver of the requirement to obtain consent has been approved in accordance with reference (b). The Marine Corps limits HSR under its purview to adults who can give their own informed consent. Refer to reference (d) for specific information regarding service members under 18 and their status as adults.

There may be some elements of confidentiality or anonymity that conflict with a military subject's (or researcher's) responsibility to report knowledge of criminal conduct or violations of the Uniformed Code of Military Conduct. Where this conflict exists, informed consent documents shall contain specific language pertaining to the limits of confidentiality.

The elements of informed consent are presented below. Depending on the research, ongoing discussion with and education of subjects may continue long after the original informed consent is obtained. For additional requirements on informed consent, refer to reference (b) and (c).

17.1 General Informed Consent Requirements

1) Unless a waiver has been approved, voluntary informed consent must be obtained from each prospective subject and include all the elements of informed consent found in Section 15.2 (Required Elements of Informed Consent).
2) Information must be given in a language and manner understandable to the subject and the consent process must include:
    a. Sufficient time for the prospective subject to read or hear the information at a reasonable pace.
    b. Sufficient time for the prospective subject to ask questions and, if necessary, a private space in which to ask them.
3) The IRB may require that additional information be given to the subject when the information would meaningfully add to the protection of the rights or welfare of the subject.
4) Investigators must use the informed consent document with the IRB approval stamp. If the use of the IRB stamped form is not possible due to the method of transmission and collection of informed consent, the PI shall provide the IRB with a copy of the consent document that was used for comparison with the approved form. The IRB Chair shall verify that the content of the two forms is the same. An example of this situation would be on-line administration of consent, where the subject's consent is obtained by "clicking" on an acknowledgement box prior to proceeding to the data collection / survey.

5) When documentation of consent is required, documentation will include date, subject name and signature, and researcher name and signature. For certain types of research, the IRB also may require the signature of a witness.

6) For exempt research, approval of a consent document or script by the IRB and documentation of informed consent are not explicitly required. However, the IRB may impose approval and/or documentation requirement for projects in which doing so is in the best interest of the subjects.

7) For non-exempt research, the IRB may waive the requirement for informed consent documentation as outlined in reference (b) only if:

    a. The research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context, or

    b. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality.

    c. In cases in which the documentation is waived, the IRB shall require that informed consent be obtained orally, and a script of such informed consent must be submitted to the IRB. The IRB may require the investigator to provide subjects with a written statement regarding the research and document the informed consent process in research records, field notes, etc. For surveys that are administered via the internet, informed consent documentation may be met by having the subject select an appropriate block on the informed consent page of the survey. The subject must be blocked from proceeding with the survey in the absence of the "acknowledgement" block being indicated. The IRB shall also determine applicability and implementation of 10 USC 980, reference (a).

8) An investigator shall seek informed consent only under circumstances that provide the prospective subject sufficient opportunity to consider whether to participate in the study, and that minimize the possibility of coercion or undue influence.

9) Informed consent may not include any exculpatory language through which the subject is made to waive, or appear to waive, any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, or the government or its agents from liability for negligence.

10) Nothing in this policy shall be taken to preempt any guidance that requires disclosure of additional information to subjects.

11) Per Appendix F, unless a waiver of informed consent documentation is approved by the IRB: a) investigators must use the IRB-stamped informed consent document and b) investigators will ensure participants are given a copy of the IRB approved informed consent document to keep.

12) PIs may request a waiver or alteration of consent, consistent with the requirements in Appendix F, in the section of the protocol addressing consent. The request must provide a rationale with specific reference to the criteria in Appendix F.

13) PIs may request a waiver of the requirement to document informed consent, consistent with the requirements in Appendix F, in the section of the protocol addressing consent.

The request must provide a rationale with specific reference to the criteria in Appendix F.

17.2 Required Elements of Informed Consent

17.2.1 Key Information

The first paragraph of the informed consent document or informed consent script should be identified as "Key Information**."** Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why they might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that is easy for the prospective subject to understand.

1) At a minimum, the following information shall be provided in the informed consent process to every subject involved in any research covered by this policy and associated procedures (note that the information need not be presented in this order):
    a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental
    b. A description of any reasonably foreseeable risks or discomforts to the subject
    c. A description of any benefits to the subject or to others which may reasonably be expected from the research
    d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
    e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
    f. For research involving greater than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
    g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
    h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
2) One of the following statements about any research that involves the collection of identifiable private information:
    a. A statement that identifiers might be removed from the identifiable private information and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized

representative, if this might be a possibility; or

b. A statement that the subject's information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

17.2.2 Additional Elements

When appropriate, one or more of the following elements of information shall be provided to each subject.

1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
3) Any additional costs to the subject that may result from participation in the research
4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6) The approximate number of subjects involved in the study.

17.2.3 Greater Than Minimal Risk

When exposure to greater than minimal risk is involved, the following additional elements of information shall be provided to each subject in the informed consent:

1) An explanation as to whether any compensation is available and an explanation as to whether any medical treatment is available, if injury were to occur, what those injuries may be, or where further information may be obtained.
2) The name, position, phone number, and email address of the designated ombudsperson, if recruitment and consent is being conducted in group settings or if the IRB has determined that the use of an ombudsperson is appropriate.

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18 Continuing Review, Progress Reports, and Reporting Requirements

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18.1 General Guidance

To ensure ongoing awareness of all research conducted under its oversight, the IRB shall conduct a Continuing Review (CR) of or review a Progress Report (PR) for all research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, with the option to alter this requirement for exempt research as described in Chapter 14. The purpose of CRs and PRs is to provide sufficient in-stride information for the IRB to determine whether the research is proceeding according to the approved protocol and timeline and whether or not there have been any challenges or problems that warrant greater attention from the IRB.

PIs shall be notified, in the approval document for the initial review of their protocol, whether a CR or a PR is required. Unless otherwise documented, the Marine Corps requires an annual PR for all non-exempt minimal risk research and for all exempt research.

Greater than minimal risk research shall require an annual CR unless more frequent review is specified in the initial review approval documents or in later documentation. The IRB shall direct expired research be discontinued unless an administrative extension of the deadline for CR submission is granted by the IRB Chair with notification to the IO. Administrative extension of CR due dates is prohibited.

The IRB may choose to require PRs or CRs more frequently than annually for some protocols on a temporary or permanent basis based on a vote of the convened IRB. More frequent than annual reporting requirements may be considered based on a variety of factors such as the specific risks in a protocol, previous non-compliance, adverse events, or UPIRTSOs, past problems with PI turnover, PI experience level, or other factors.

18.2 Progress Reports

1) The IRB Administrator shall provide the PI with a reminder that a PR is due at least 40 business days in advance of the research approval anniversary date and shall provide the PI with the format for the required PR.
2) The PI is required to submit a PR for their research annually (or at another interval determined by the IRB Chair or IRB) at least 10 business days before the due date set by the IRB Chair or IRB. The PI shall submit a PR package, to include an IRB Action Request and a PR to the IRB Administrator.
3) Failure to submit the PR at least 10 business days before the designated due date may result in the IRB directing that work on the protocol be stopped and reviewing the matter as non-compliance with reference (d). The IRB may exercise discretion in when and how to address late PRs based on the specific protocol and circumstances. However, at a minimum, if the PR is not received by the due date, the issue shall be discussed at the next IRB meeting and the IRB shall provide formal notification to the PI and the PI's supervisor that they are in violation of this policy, what corrective actions are needed, by what date the corrective actions must be complete, and the consequences of failing to

complete them.

4) PRs shall be submitted to the convened IRB for information. For exempt protocols and protocols reviewed under expedited procedures, the EDO or IRB Chair, as applicable, may review and acknowledge or approve the PR with notice to the PI that the PR will be provided to the convened IRB at the next convened meeting and that board members may raise questions or concerns that the PI will be required to address. If the convened IRB directs additional action or raises questions for the PI, these shall be communicated to the PI by the EDO, vice chair, IRB Chair, or IRB Administrator as appropriate.

5) PRs do not require the approval of the IO.

6) All reports and documentation related to PRs must be submitted to DON HRPP for HQ level review.

18.3 Continuing Reviews

When required by the IRB and for all greater than minimal risk research, a CR must be properly completed and re-approval granted prior to the end of the approval period to avoid interruption of the research. The CR shall be conducted in a manner similar to the initial review, with review of documents at a convened meeting. An expedited CR procedure may be used for all research protocols originally approved using an expedited review process or for protocols that qualify for expedited review under category 8 or 9 of Appendix B. Unlike the original protocol reviews, which assess potential impact of the protocol as planned, CRs involve a complete re-evaluation of the risk-benefit ratio based on actual experience with the conduct of the research and the actual impact on human subjects to date.

1) The USMC IRB shall provide the PI with a reminder that a CR is due at least 40 business days in advance of the research approval anniversary date and shall provide the PI with the format for the required CR.

2) The PI is required to submit a CR for their research to the IRB Administrator at least 20 business days prior to the expiration date to allow the IRB sufficient time to review the CR. The CR package shall include an IRB Action Request and a CR.

3) If a CR is submitted after the expiration date, it must include an explanation for the late submission and a statement confirming that no human subject research occurred after the expiration date.

4) For CR, the IRB shall consider all information in an overall perspective when making their recommendations for continuation. The IRB shall:

    a. Review the CR and any other documentation submitted by the PI.

    b. Determine whether or not the risk-benefit ratio has changed unfavorably and whether or not the actual risks are no greater than as originally anticipated.

    c. Determine if the informed consent process has been both adequate and properly documented using only the IRB approved consent documents. Make recommendations to correct any deficiencies.

    d. Verify that subjects enrolled fit selection and exclusion criteria.

    e. Consider whether there has been adequate protection of the subjects' privacy and

confidentiality of data, including storage and handling of previously collected data that are protected under the protocol and informed consent agreement.

f. Specifically approve a new updated informed consent document showing the new expiration date, unless the IRB did not originally require informed consent documentation.

g. Document its discussions, recommendations, and votes on each CR separately in the minutes.

h. Reclassify the risk of a protocol if, in their judgment, a new classification better captures the actual risk to subjects.

i. Ensure there has been prompt reporting of proposed changes in research and that the PI has not implemented changes without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

5) The IRB may take one of the following actions:

   a. Approve continuation of the research without change.

   b. Add requirements for continued approval.

   c. Suspend (temporarily) or terminate (permanently) the research effort.

   d. Verify from sources other than the investigators that no material changes have occurred since previous IRB review.

6) The CR package shall be forwarded to the IO for review based on the IO review criteria set out in Chapter 4.

7) All reports and documentation related to the CR must be submitted to DON HRPP for HQ level review.

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19 Scientific or Scholarly Review

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Per references (b) and (e), an independent review of research for scientific merit or scholarship is required prior to IRB review for all non-exempt HSR. Appropriate individual(s), committees and/or groups other than the IRB must complete a scientific or scholarly review for ensuring scientific or scholarly soundness. Since each discipline contains distinct theories and methods, there can be no one absolute standard against which all studies can be assessed.

Likewise, not all research involving human subjects will be scientific and the soundness of such studies must be assessed using standards appropriate to the proposed approach. Determining the soundness of a study requires expert judgment about the degree to which the theoretical and methodological approach in a research design is appropriate to the topic and specific questions being investigated.

PIs are responsible for obtaining a scientific or scholarly Review, using the Scientific/Scholarly Review Template, prior to submission of their research protocol to the IRB for review. The PI may choose from a wide variety of resources for such a review. Acceptable sources for this review may include but are not limited to subject matter experts in the field of the research or local scientific review boards. Reviewers may not be members of the research team or the supervisor of the PI. Reviewers may not have a conflict of interest, such as a financial or other stake in the research or being a family member of the PI.

Qualifications of the reviewing individual or body must be included in the review package. Qualifications include at least reviewer titles, location, area of expertise, relationship to PI, and a statement supporting their appropriateness as a reviewer.

Using the Scientific Review Template, the scientific or scholarly reviewer will provide an assessment to the PI that provides explicit responses to the questions below. The reviewer will include a recommendation either that the IRB initiate its review or provide feedback to the PI regarding changes to the protocol to satisfy the scientific or scholarly review. The reviewer shall provide copies of the review to both the PI and the IRB Chair or Administrator.

1) The scientific or scholarly review should consist of a review of the protocol, augmented by interactions with the principal investigator, as needed, for clarification.

2) The reviewer should consider the following questions when going through the protocol:

    a. Purpose(s): Is / are the objectives / hypothesis clearly stated? What important problem or area of knowledge does the research address? How will scientific or scholarly knowledge be advanced if the research goals are achieved?

    b. Approach:

        i. Theoretical Basis or Conceptual Framework. Assess the adequacy and appropriateness of the project's theoretical basis or conceptual framework for the aims of the project.

        ii. Data Gathering Methods and Sampling. Assess the appropriateness of the methods proposed for gathering data in terms of the aims of the project and the research context. Is the sampling strategy and sample size

appropriate for the project?

iii. Data Analysis Methods. Assess the appropriateness of the methods proposed for analyzing the data in terms of the aims of the project and the type(s) of data that will be gathered.

iv. Design Limitations. Are the limitations of different aspects of the design / approach clearly articulated? Please explain the basis for your determination.

v. Overall Design Appropriateness. Are the types of results this design can produce are appropriately matched with the scientific, scholarly, or programmatic claims the researchers hope to make? If they are not appropriately matched please explain why.

vi. PI Design Awareness. Does the investigator recognize and acknowledge potential problem areas? How has the PI addressed those potential problem areas and what alternatives were considered?

vii. Subject Selection. Are the inclusion and exclusion criteria appropriate for the aims of the research and the population?

viii. Subject Availability. Are sufficient subjects available to support the research? Do you anticipate any problems recruiting sufficient subjects to support the research and, if so, how does the protocol address those potential problems?

c. Investigator:

i. Qualifications. Briefly describe how the qualifications of the PI and research team are adequate to carry out this work. If necessary, is there an appropriate plan to train the research team and other support personnel?

ii. Supervision. If the PI is using a research team or research support personnel, explain whether the PI is trained and suited to supervise the team.

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20 Non-compliance, Misconduct, Adverse Events, Unanticipated Problems

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This chapter addresses issues with investigator conduct and problems that may occur during research.

20.1 Investigator Conduct

Investigators are expected to conduct research and record-keeping in compliance with this policy and procedures and its references without the need for explicit direction. Failure to do so may constitute non-compliance or misconduct.

Non-compliance refers to failure to comply with the USMC HRPP Policy and Procedures and its references. Misconduct is defined in reference (n) as detailed in section 20.3.

20.2 Allegations of Non-compliance

All participants, including human subjects, researchers, or support personnel shall be informed of their right to report concerns about the conduct of research to the PI, IRB Chair, or IRB vice chair. If a report is made to the PI or a vice chair, that person must inform the IRB Chair. The IRB Chair shall review all reports. If a report may constitute an allegation of non-compliance, the USMC IRB and an IO shall review the report and take action, if appropriate. In general, non-compliance refers to failure to comply with the USMC HRPP Policy and Procedures or its references. Allegations of non-compliance may be determined to be:

1) Minor Non-Compliance. While all non-compliance is of concern and must be addressed, some non-compliance is neither serious nor continuing. For example, minor administrative deviations from a protocol, procedure, or policy that did not have the potential to affect the rights or risks to subjects and do not indicate deliberate disregard for procedures or policy may be considered minor non-compliance. Minor non-compliance must be addressed by the PI and, if appropriate, the IRB may require additional training for the PI and associate investigator or documentation of actions taken to address the problem. However, minor non-compliance does not require the IRB to initiate a formal investigation.

2) Serious Non-Compliance. Serious non-compliance is failure of a person, group, or institution to act in accordance with this instruction and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data. If a preliminary review of a report of potential non-compliance indicates that it may be serious, the IRB shall initiate a formal investigation.

3) Continuing Non-Compliance. Continuing non-compliance is pattern of non-compliance that suggests the likelihood that, without intervention, instances of non-compliance will recur, a repeated unwillingness to comply, or a persistent lack of knowledge of how to comply. If a preliminary review of a report of potential non-compliance indicates that it may be continuing, the IRB shall initiate a formal investigation.

4) Combinations and Repetitions. In some cases, an allegation may indicate different types of issues or non-compliance. In all cases in which serious and/or continuing non-compliance is suspected, the IRB shall initiate a formal investigation. The IRB also must consider the specific history with the PI. For example, if a PI has repeatedly had minor compliance issues within one protocol or across multiple protocols, the IRB may determine that the repetition may constitute continuing non-compliance and initiate a formal investigation.

The IRB Chair shall report the initiation of all formal investigations and report results, regardless of the findings, to DON HRPP and appropriate research sponsors.

The IRB Chair shall brief the IRB at each convened meeting on any actions taken related to potential or actual non-compliance.

20.3 Allegations of Research Misconduct

Research misconduct is defined in reference (n) as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion."

Some allegations of misconduct may constitute non-compliance with this policy and associated procedures, in which case the report shall be handled as an allegation of non-compliance. Types of misconduct that do not fall within the scope of the USMC HRPP, such as plagiarism in a publication, shall be referred to the appropriate organization for action. In all cases, the report and decision regarding investigation or referral shall be documented in the USMC HRPP's records and reported to other officials and agencies if required.

20.4 Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO)

UPIRTSOs are any incident, experience, or outcome that meets ALL three of the following conditions:

1) Is unexpected (in terms of nature, severity or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subjects populations being studied.
2) Is related or possibly related to participation in the research (in this policy "possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
3) Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

Upon identification of the UPIRTSO, the PI shall verbally notify the IRB Chair immediately and submit an Unanticipated Problem/Adverse Event Report with an IRB Action Request to the IRB Chair within 24 hours of the event. The report shall include the PI's (and that of the research ombudsperson, if applicable) evaluation of the experience and recommend corrective action. If the IRB Chair does not concur with the recommendations, additional safeguards may be

required. The Chair shall also provide a copy to the IRB, who may in turn choose to impose additional safeguards. The Unanticipated Problem/Adverse Event Report and IRB recommendation shall be forwarded to the IO within seven working days. The IO may impose additional safeguards but may not remove or reduce any safeguards imposed by the IRB. The IRB Chair shall report final decisions, endorse the PI's report, and forward the documentation to DON HRPP within 15 business days of the discovery of the UPIRTSO.

Not all unanticipated problems in research are UPIRTSOs. Investigators may experience unanticipated problems, such as challenges getting approval to use a particular type of analytic software, that do not meet the definition of a UPIRTSO. Such problems do not need to be reported. However, if a PI has any questions regarding whether or not a problem meets the definition of UPIRTSO, they should contact the IRB Chair immediately to assist in determining what reporting, if any, is required.

20.5 Adverse Events and Serious Adverse Events

An adverse event is any untoward or unfavorable occurrence associated with the conduct of a research project, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms. For Food and Drug Administration (FDA)-regulated research, the definition of adverse event should be followed.

Serious adverse events are those with serious effect or potential for serious effect, whether or not the event was expected to occur during the research. Obvious serious events include death, hospitalization, disability, severe emotional distress, or significant injury or illness. They also include deviations from research protocol, which increase potential risk to subjects. Anticipated deviations from research protocol must be pre-approved by the IRB through the protocol modification process.

PIs must ensure that investigators (or any research personnel who interact with subjects) take action immediately to avoid further adverse events or harm to the subject. If appropriate, research should be halted until problems can be identified and resolved. The PI shall verbally notify the IRB Chair immediately upon identification of the serious adverse event and submit an Unanticipated Problem/Adverse Event Report with an IRB Action Request to the IRB Chair within 24 hours of the event. The report shall include the PI's (and that of the research ombudsperson's, if applicable) evaluation of the experience and recommend corrective action. If the IRB Chair does not concur with the recommendations, additional safeguards may be required. The Chair shall also provide a copy to the IRB, who may in turn choose to impose additional safeguards. The Adverse Event Report and IRB recommendation will be forwarded to the IO within 10 business days. The IO may impose additional safeguards but may not remove or reduce any safeguards imposed by the IRB. The IRB Chair shall report final decisions, endorse the PI's report, and forward the documentation to DON HRPP within 15 business days of the discovery of the serious adverse event.

Not all adverse events in research need to be reported and/or corrected, as some, such as minor side effects, may have been anticipated in the protocol and covered in the informed consent. However, if a PI has any questions regarding whether or not a problem meets the definition of a

serious adverse event, they should contact the IRB Chair immediately to assist in determining what reporting, if any, is required.

20.6 Intersection of Unanticipated Problems and Adverse Events

There is a partial overlap in the definitions of unanticipated problems and adverse events. For example, some adverse events, such as minor side effects, may have been anticipated in the research protocol and explained in the informed consent process. Likewise, some unanticipated problems, such as a financial problem experienced by a subject that is not caused by the research, do not meet the criteria for an adverse event.

If a PI is unsure about the categorization of a problem or event, they should contact the IRB Chair immediately to assist in determining what reporting, if any, is required.

20.7 IRB Actions

The IRB Chair and IRB shall, in all cases, act in ways that are in the best interest of subjects. Depending on the nature of the UPIRTSO or Adverse Event, the IRB Chair may direct that the PI temporarily halt research until further information is available and/or until the IRB has the opportunity to review the report. The IRB may direct corrective actions including, but not limited to changes in the protocol and informed consent language or process, assignment of an ombudsperson, suspension of the research, or termination of the research. If the IRB Chair or IRB see evidence that the UPIRTSO or Adverse Event resulted from non-compliance or misconduct, they may initiate an investigation.

When an investigation is initiated, the IRB Chair shall consult with at least one vice chair regarding the appropriate individual(s) to conduct the investigation. Any individual involved in conducting an investigation shall be free from conflicts of interest and shall conduct a review of applicable regulations, policies, and guidelines prior to starting investigative activities.

Investigations may take different forms based on the details of the report or allegation. The structure and intent of the investigation shall be documented and the investigation shall be conducted in ways that are transparent to the PI, the PI's supervisor (if applicable), the organizational vice chair (if applicable), and the board.

Investigative activities may not be recorded without the permission of all individuals involved. Permission should be included in the recording or via email in advance so that it can be included in the record of the activity.

Investigations shall focus on specific requirements of policies applicable to the situation. Only regulation- or policy-driven requirements may be included as part of the official findings. Individuals involved in conducting the investigation and other board members may offer additional recommendations to the PI verbally or in a separate, recommendations section of the report.

20.8 Summary Reporting

Summaries of all allegations of non-compliance, research misconduct, UPIRTSOs, serious adverse events, and unanticipated problems must be submitted to the IRB along with each subsequent Continuing Review or Progress Report and the Final Report.

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21 IRB Review Requirements for External Organizations

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The USMC IRB may review protocols in which the Marine Corps is not involved, provided that appropriate agreements are established.

The USMC IRB may serve as the reviewing IRB for institutions that have obtained an appropriate institutional assurance. An institution does not need to list the USMC IRB as a reviewing IRB on its assurance for a one-time review. An Institutional Agreement for IRB Review (IAIR) is used in this case. The only time an institution will need to list the USMC IRB on its assurance is if the USMC IRB will be the permanent reviewer for all of their work. The Marine Corps and the performing institution must have a signed IAIR.

In limited circumstances, at the discretion of the IRB Chair, the USMC IRB may conduct applicability reviews for contractor-led projects and may provide oversight for contractor-led human subjects research after an appropriate agreement is established with the vendor or individual. Additional details are provided in Chapter 22.

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22 Review of Projects by External/Extramural Individuals and Organizations

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The USMC HRPP reviews all projects proposed by external researchers that will involve gathering information from or about USMC personnel (military and civilian) or the use of data about USMC personnel. The only exceptions to this are projects funded by M&RA or MCSC, which are reviewed by the HRPOs in those organizations. Review is required even if the reviewing IRB has determined that a project is not human subjects research. These reviews ensure that DoD- and USMC-specific requirements and considerations are addressed and ensure that appropriate leaders are aware of the project and willing to provide necessary support.

Observation of USMC personnel is considered gathering information from or about them, not merely use of facilities. Therefore, review of observational projects is required.

If the only support requested is the use of USMC facilities or equipment and no information will be gathered from or about USMC personnel, review is not required. Project leads requesting only the use of facilities or equipment are advised to coordinate with appropriate contacts early to ensure that the leaders responsible for the facilities and/or equipment are able and willing to provide the necessary support.

Supported vs. Assisted Projects: The category "USMC Supported Projects" includes all projects supported by the Marine Corps through funding, providing personnel to assist with the project (e.g., research team members), making personnel available to participate, making data available, and/or providing logistical support. The category "USMC Assisted Projects" is a subset of USMC-Supported Projects that includes projects conducted by external individuals or organizations for which the USMC provides only non-financial support, such as the ability to recruit participants or access data.

HRPO vs Administrative Review: If the project is funded by the USMC, review by a Human Research Protection Official (HRPO) is required. If the project is funded by Manpower and Reserve Affairs (M&RA) or Systems Command (MCSC), this review is conducted by the HRPO in the funding organization. If the funding is from any other USMC source, the review is conducted by a HRPO within the USMC HRPP. If the project is not funded by the USMC, the USMC HRPP conducts an Administrative Review. Requirements for each type of review are described below.

22.1 Projects Funded by the USMC (USMC Supported): HRPO Review

Any project funded by the USMC that will involve gathering information from or about USMC personnel (military and civilian) or the use of data about USMC personnel, such as existing personnel datasets, must be reviewed by the appropriate HRPO.

This review is required even if the reviewing IRB has determined that a project is not human subjects research. Researchers whose projects have received a "not human subjects" determination should contact the appropriate HRPO to determine what materials are required for the submission.

Materials should be submitted to the USMC, M&RA, or MCSC HRPP for HRPO review, depending on funding source. At the reviewing HRPO's discretion, partial materials may be

submitted to allow for preliminary review while final materials, such as letters of support, are obtained. Do not make partial submissions without consulting with the appropriate HRPO.

For HRPO reviews conducted by the USMC HRPP, the following documentation is required at a minimum (additional detail is available from the USMC HRPP):

1) A copy of the full protocol or project plan. This must include the exact materials reviewed by the performer's IRB, including (when applicable) the recruitment plan, consent documents, and any information gathering instruments, such as surveys, sample interview questions, etc.
2) Results of IRB review. If the project was determined to not be human subjects research, the results must include the specific rationale and policy basis for the determination. If the project is human subjects research, the results must include the risk level and, if applicable, the exemption or expedited review category, along with the rationale for that determination. If a waiver of consent or of the requirement to obtain documentation of consent has been granted, the specific policy basis must be cited.
3) If the reviewing IRB is not a DoD IRB and the project is human subjects research, documentation of ethics training, such as CITI training certificates, and researcher qualifications, such as resumes or curriculum vitae.
4) A detailed description of the specific USMC support requested.
    a. Consider not only requests for USMC personnel participation (including what you will ask them to do and how long it will take), but also any support you may request to access the facility, schedule rooms, assist with distribution of recruiting materials, etc.
5) A copy of the funding agreement, e.g., research grants, contracts, Cooperative Agreements, Cooperative Research and Development Agreements (CRADAs), Work for Private Party Agreements, Educational Partnership Agreements, involvement in Small Business Innovative Research (SBIR) or other transactions, hereafter collectively considered "binding agreements." The binding agreement must show that it includes the required human subjects research language as per reference (r).
    a. To facilitate review, submitters are advised to let the reviewing HRPO know the page number(s) where the required language can be found.
6) If the binding agreement does not specify the type of research or project planned, a copy of the statement of work, task order, or similar document showing that the planned project is consistent with the binding agreement. For example, a contract may make a general statement about supporting research and analysis with a task order providing more detail about conducting research interviews at USMC bases.
7) For all non-exempt human subjects research, the Federalwide Assurance (FWA) or DoD Assurance number of the researcher's organization and the reviewing IRB's registration number with expiration dates. If unsure where to find these, check with the reviewing IRB.
8) Letter(s) of support from the appropriate commanding officer(s) indicating permission to recruit volunteers to participate, access data, and/or any required logistical support. The letter(s) must include the project title. The letter(s) must be signed by the immediate commander(s) at the O-5 / O-6 level, or highest common commanding officer(s). For example, if the subjects are to come from more than one battalion within a regiment, the approval would come from the regimental

commander. “By direction” approval or approval by other staff officers signing under their title does not fulfill this requirement. At the discretion of the Director of the USMC HRPP, based on the specific details of the protocol, the following alternatives to formal letters of support may be allowed:
   a. Emails from COs of affected units.
   b. A flag officer-level letter of support for projects involving a broad range of commands (e.g., a service-wide survey).

9) Approval from the commander(s) of the installations or facilities where the research will take place may be required in certain cases, such as projects where recruitment or other research activities may take place across several commands at an installation. Consult with the USMC HRPP to determine if this requirement applies.

10) As appropriate to the details of project, documentation that the project is in compliance with reference (d) and its references (e.g., provisions for medical care, use of DoD personnel as experimental subjects, etc.).

Additional guidance for projects using USMC data is provided in Appendix J.

The HRPO may require additional information and documentation based on the details of the project. Other required USMC or higher-level reviews may require additional documentation. For example, the USMC Survey Program may require a letter of support from a general officer or SES. Researchers or project leads should communicate with other reviewing bodies for details.

22.2 Projects Not Funded by the USMC (USMC Assisted): Administrative Review

Any project not funded by the USMC that will involve gathering information from or about USMC personnel (military and civilian) or the use of data about USMC personnel, such as existing personnel data sets, must undergo an Administrative Review by the USMC HRPP.

This review is required even if the reviewing IRB has determined that a project is not human subjects research. Researchers whose projects have received a “not human subjects” determination should contact the USMC HRPP to determine what materials are required for the submission.

A USMC Administrative Review is not an IRB review but rather a second level review to ensure the extramural performer has addressed DoD- and USMC-specific requirements and considerations.

Materials should be submitted to the USMC HRPP. At the discretion of the Director of the USMC HRPP, partial materials may be submitted to allow for preliminary review while final materials, such as letters of support, are obtained. Do not make partial submissions without consulting with the USMC HRPP.

At a minimum, documentation must include (additional detail is available from the USMC HRPP):

1) A copy of the full protocol or project plan. This must include the exact materials reviewed by the performer’s IRB, including (when applicable) the recruitment plan, consent documents, and any information gathering instruments, such as surveys, sample interview questions, etc.

2) Results of IRB review. If the project was determined to not be human subjects research, the results must include the specific rationale and policy basis for the determination. If the project is human subjects research, the results must include the risk level and, if applicable, the exemption or expedited review category, along with the rationale for that determination. If a waiver of consent or of the requirement to obtain documentation of consent has been granted, the specific policy basis must be cited.
3) If the reviewing IRB is not a DoD IRB and the project is human subjects research, documentation of ethics training, such as CITI training certificates, and researcher qualifications, such as resumes or curriculum vitae.
4) A detailed description of the specific USMC support requested.
    a. Consider not only requests for USMC personnel participation (including what you will ask them to do and how long it will take), but also any support you may request to access the facility, schedule rooms, assist with distribution of recruiting materials, etc.
5) For all non-exempt human subjects research, the Federalwide Assurance (FWA) or DoD Assurance number of the researcher's organization and the reviewing IRB's number with expiration dates. If unsure where to find these, check with the reviewing IRB.
6) If the project is DoD-funded, a copy of the HRPO review conducted by the funding organization. If this is not yet available at the time of submission, provide the name and contact information of the HRPO who will be conducting the review.
7) A flag officer-level letter of support from the appropriate HQMC department with oversight of the topic or the first flag officer in the subjects' chain of command. "By direction" approval does not fulfill this requirement. The letter requires the signature of a general officer, SES or other flag-level officer and must include the title of the project. This requirement may be waived by the Director of the USMC HRPP only if approved by the USMC IO.
8) Letter(s) of support from the appropriate commanding officer(s) indicating permission to recruit volunteers to participate, access data, and/or any required logistical support. The letter(s) must include the project title. The letter(s) must be signed by the immediate commander(s) at the O-5 / O-6 level, or highest common commanding officer(s). For example, if the subjects are to come from more than one battalion within a regiment, the approval would come from the regimental commander. "By direction" approval or approval by other staff officers signing under their title does not fulfill this requirement. At the discretion of the Director of the USMC HRPP, based on the specific details of the protocol, the following alternatives to formal letters of support may be allowed:
    a. Emails from COs of affected units.
    b. A flag officer-level letter of support for projects involving a broad range of commands (e.g., a service-wide survey).
    c. In exceptional circumstances only - direction from the Director of the USMC HRPP to the PI to conduct appropriate coordination with unit COs. The PI may be required to document the support at a later time. Note that if this option is exercised by the Director of the USMC HRPP, researchers are still required to ensure affected commands are able and willing to support the research, as

required in reference (d). Failure to do so may result in USMC HRPP approval being withdrawn.

9) Approval from the commander(s) of the installations or facilities where the research will take place may be required in certain cases, such as projects where recruitment or other research activities may take place across several commands at an installation. Consult with the USMC HRPP to determine if this requirement applies.

10) As appropriate to the details of project, documentation that the project is in compliance with reference (d) and its references (e.g., provisions for medical care, use of DoD personnel as experimental subjects, etc.).

Additional guidance for projects using USMC data is provided in Appendix J.

The USMC HRPP may require additional information and documentation based on the details of the project. Other required USMC or higher-level reviews may require additional documentation. Researchers or project leads should communicate with other reviewing bodies for details.

The USMC HRPP Director, with the concurrence of the USMC IO, may waive the requirement for Administrative Review and require only notification for certain categories of projects or for individual projects. Such waivers are granted only in exceptional circumstances and for the benefit of the service. Waivers typically are not granted based on researcher timelines, funding timelines, or delays researchers have experienced in other review processes.

22.3 Student Projects Conducted as Part of Studies at External DoD or Civilian Schools

1) All students who are conducting research or projects as part of their studies at DoD schools outside the Marine Corps (e.g., Naval Postgraduate School or Army War College) or civilian schools are considered external performers even if they are government personnel and their attendance is funded by their service or agency. Their submissions are processed as though they were civilian students without government affiliation.
   a. Projects conducted by students at Marine Corps schools, including Marine Corps University, are reviewed by the USMC IRB. Refer to Chapter 7.

2) The USMC HRPP makes every effort to facilitate student research whether by government personnel or by unaffiliated students. Such projects typically undergo Administrative Review and are subject to the same requirements listed in section 22.2. If a DoD funding agreement is involved, the student should reach out to their local IRB and the USMC HRPP for additional guidance.

3) Students Who Are Government Personnel: In developing a project plan or human subjects research protocol, students who are government personnel should be very careful to ensure that it is clear they are conducting the project in their student capacity, not their official capacity. This includes using their student or personal contact information on all materials participants may see, such as recruiting flyers or emails, consent forms, etc. and not using official rank or title in these materials.

4) Students Who Are Not Affiliated with Government: Students not affiliated with the government seeking to conduct research or projects involving USMC personnel or data should budget ample time for navigating required reviews. In addition to their school's IRB review and USMC Administrative Review, there may be other required reviews and approvals depending on the details of the project. These reviews can add

weeks or months to the time needed to be fully approved to get started. Students are encouraged to talk with their points of contact within the USMC and the USMC HRPP early in the design process to determine what may be required.

22.4 Contractor-Led Projects in Support of USMC Organizations

1) Contractors leading projects or research in support of USMC organizations are considered external performers and must undergo either HRPO Review or Administrative Review based on the funding source. This includes arranging for IRB services through a civilian institution or private s. The alternative is to identify a USMC government civilian, Marine, or member of another uniformed service currently assigned to the USMC who is qualified and able to serve as a PI. If a government PI is available and able to fulfill all duties outlined in Chapter 7, the project can be submitted for USMC IRB review as described in Chapters 7 and 12.
2) In limited circumstances, at the discretion of the IRB Chair, the USMC IRB may conduct applicability reviews for contractor-led projects and may provide oversight for contractor-led human subjects research after an appropriate agreement is established with the vendor or individual. The USMC IRB is not required to provide these services and is not resourced or staffed to do so. It provides IRB services to contractor-led projects or research only in unusual circumstances and only when its existing workload allows. Requests to provide IRB services for contractor-led projects must be made by a DoD organization, not the contracting vendor.

22.5 Considerations for Requesting Letters of Support

The USMC HRPP does not require a specific format for letters of support, as each command has its own staffing and formatting requirements. All letters must include the project title (as listed on the IRB-approved protocol) and must be signed by the actual billet holder, not "by direction."

In some cases, flag officers may wish to see commanding officer-level letters of support before providing their own letter. In other cases, the letters can be pursued concurrently. Researchers should consult with the staff in each command to determine the appropriate sequence.

Researchers should consult the staff of each command to determine the exact materials that should be submitted with a request for a letter of support. It is critical to ensure the recipient has a clear understanding of the impact on their command and personnel if they agree to support. Keep in mind that any support provided to research, even if only letting personnel participate, assembling a dataset for researchers, or having a staff member send an email with a link to a survey, takes time away from the core duties of USMC personnel. Commands often find the following types of information valuable:

- A succinct, clear description of the project.
- Details of the support requested including information such as:
    - The types and numbers of USMC personnel who will be recruited.
    - How much time each person will spend participating.
    - What participants will be asked to do.
    - A description of any datasets being requested and whether the researchers want the data to be de-identified by the data holder prior to release.
    - What other research activities may take place at the command, such as informational briefings, recruitment, etc.

    - When research activities will take place and whether the schedule can flex to accommodate command schedules.
    - Any logistical support needed, such as rooms for the research, help with access to base, or circulating an email with a link to a survey. (Do not assume that the command will be able to make personnel available at the last minute to assist the research team with things like figuring out where to park, finding rooms, etc. If a point of contact will be needed to provide assistance before and/or during the project, include a description in the request.)
- How the research is funded.
- A brief description of how the research will benefit the USMC and/or other stakeholders, such as DON, DoD, or the broader society.
- When and how research results will be made available to the USMC.
- What will be done with the data when the research is complete.
- Whether or not USMC will have access to the data or have the option to establish a data sharing agreement.

22.6 Considerations for USMC Organizations Funding Research or Providing Letters of Support: Ensuring Awareness of Data Uses

Research involving USMC personnel and their data can benefit the USMC, as well as other stakeholders including DON, DoD, and the broader society. Materials capturing results, such as reports and publications, are traditional outcomes of research. However, many research efforts also produce data sets that have value beyond one specific project. Some researchers are approved by the reviewing IRB to retain data for other uses and to share it with others.

To make informed decisions about endorsing projects and providing access to USMC personnel or their data, any USMC organization entering into a binding agreement for research or agreeing to provide access to USMC personnel or their data should carefully consider the following:

1) Access to data. Some data gathered during research activities may be valuable to the Service for internal research and analysis. USMC organizations should consider including access to de-identified data as a deliverable (or similar requirement) or requesting that the researchers establish a data sharing agreement with the USMC.
2) Third Party Data Rights: Projects involving the use of personal technologies (e.g., wearable devices, applications, etc.) may require USMC personnel to sign a user agreement with the technology vendor in order to participate. These user agreements may allow the technology vendor to gather, retain, use, and share the participant's personal information and data related to their physical health, mental health, behavior, and location. These agreements should be reviewed to ensure that the USMC organization funding or assisting the research is aware of how their personnel's data will be used.
3) Commercial uses of data. Some researchers use data gathered from USMC personnel for development of commercial outcomes (e.g., technologies, classes, etc.). This sometimes is desirable and an intentional part of research funding. However, it can create challenges if the USMC would like access to the de-identified data gathered from its personnel and the researcher considers the dataset proprietary. USMC organizations should consider whether or not to allow commercial uses in binding agreements. If commercial uses will

be allowed, funding organizations should consider whether or not to include data sharing with the USMC as a deliverable. When projects are not funded by the Service, USMC organizations should determine whether the funding agreement allows researchers to use project data commercially and include that knowledge in their determination of whether or not to endorse the research.

4) Data retention and data sharing plans. Many research designs involve long-term retention of data by the researchers, by their organizations, and/or in one or more data repositories. Many research designs also include the option for researchers to share their data with other researchers. Data sharing is a highly desirable practice in terms of advancing scientific knowledge. However, USMC organizations should ensure they are aware of how data gathered from USMC personnel will be used and distributed.

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23 Collaborative Research

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The USMC HRPP allows collaboration of institutions to avoid duplication of effort in research and IRB review. One of the participating institutions shall be designated in writing (within the binding agreement, if applicable, or otherwise within appropriate project materials) as having the primary responsibility for the protection of the human subjects. The institution with the primary responsibility must exercise that responsibility even during phases of the research carried out by another institution. Such reliance on other IRBs must not compromise any federal standards or DON or USMC requirements. All collaborators must ensure compliance with all relevant human subjects protection regulations at their sites. Agreements among institutions or organizations require written confirmation of an Institutional Assurance and specific assignment of responsibilities and IRB oversight.

23.1 Collaborative Research with another DoD Institution

The PI shall delineate institutional responsibilities when performing research involving human subjects in collaboration with another DoD institution. These responsibilities should include establishing written agreements for tasks such as minimizing the number of institutional review boards (IRBs) that review and approve the research. Per reference (d), when any institution relies upon another institution's IRB, there must be a written agreement defining the responsibilities and authorities of each organization in complying with the terms of each institution's Federal Assurance (e.g., an IAIR).

23.2 Collaborative Research with a Non-DoD Individual or Institution

The Marine Corps may rely on a collaborating non-DoD institution's IRB if the minimum conditions outlined in reference (d), Enclosure (3), paragraph 3.a.(8) are met.

23.3 Collaborative Effort with an Associate Investigator Not Affiliated with the Marine Corps

For the purposes of this policy, contractors who will support a research project led by a USMC PI are considered "not affiliated." Other types of unaffiliated associate investigators may include collaborators at other government organizations, civilian academic institutions, etc.

An appropriate written agreement endorsed by the appropriate IO shall be established to bring an individual investigator who is associated with the Marine Corps and conducting research, but not employed by the Marine Corps, under the appropriate DON Assurance. Typically, this is accomplished using the Individual Investigator Agreement (IIA) template. Under this requirement, a fully executed agreement would place an individual investigator under the authority of one of the Marine Corps' three HRPPs and allow a Marine Corps PI to include the individual investigator on a research project that includes HSR. This agreement normally is not intended to be used if an individual is employed by an institution that has its own Assurance; in that case, the individual would be included on a Marine Corps research project through a collaboration agreement as described above.

When approved by the IRB Chair and IO, an IIA may be used for investigators covered by a separate DoD or Federal Assurance. The selection of IAIR or IIA will be based upon the specifics of the research protocol, with concurrence of the IRB Chair and IO.

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24 Administrative Hold of Research

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In exceptional circumstances, the IRB Chair may allow administrative hold of research to accommodate unanticipated organizational staffing gaps making it impossible for the organization to assign an appropriate PI or if a PI is unexpectedly incapable of performing their duties for a period that jeopardizes the continuation of the research or the security of data and sensitive research records (e.g., sudden onset of a long-term illness or disability, being placed on administrative leave for reasons unrelated to the research, etc.). The IRB Chair is not obliged to approve an administrative hold simply because the organization meets the requirements and has a need. The IRB Chair also may consider other factors such as the current IRB workload and the availability of a vice chair to support the effort.

During administrative holds, the IRB Chair takes temporary responsibility for the project. The IRB Chair also may delegate this responsibility to a vice chair if the vice chair is willing and is knowledgeable about the project.

Temporary administrative holds are intended to preserve the continuity of research projects and prevent premature project closures in cases where the organization could not have anticipated the staffing gap or the incapacity of the PI. Due to the administrative burden placed on the person assuming temporary responsibility for the project, administrative holds shall not be allowed in cases where such gaps are the result of a failure of the PI or organization to plan for transitions or when another member of the research team could assume PI responsibilities.

Administrative hold of research is available only for exempt research and non-exempt minimal risk research for which the reporting requirement is a Progress Report rather than a Continuing Review. Administrative holds shall be allowed for no more than 60 business days without a vote of the convened IRB and, if applicable, approval of the IO.

During an administrative hold, the IRB Chair or vice chair takes temporary responsibility for the project and ensures the following:

1) All research activities including recruitment, data gathering, and work with data that have not been de-identified are stopped.
2) All required research records are transferred to the IRB Chair or designated vice chair.
3) Access to all materials containing subjects' personal information such as signed consent documents, contact lists, identity keys, notes, and datasets that have not been deidentified is limited to approved members of the research team and the IRB Chair and/or designated vice chair.

During an Administrative Hold, the individual who takes responsibility for the project:

1) May not have a conflict of interest.
2) May not vote on any IRB action related to the protocol.
3) May advise the IRB on IRB actions related to the protocol.

During an administrative hold:

1) Progress Report due dates are deferred until after the hold is lifted. A new date shall be established by the IRB Chair when a PI resumes responsibility for the protocol.

2) Changes to the protocol are not allowed except for the purposes of protecting subjects' rights, safety, or information, protecting data, or to appoint a new PI.
3) The supervisor of the former PI or other appropriate organizational leader may request that the project be closed without a new PI being appointed.

To request an administrative hold of research, the organization shall work through their vice chair or HRP point of contact to coordinate with the IRB Chair or coordinate directly with the IRB Chair if no organizational vice chair or point of contact is available. The IRB may require a particular template for such requests in the future. However, if no template is provided, requests shall include:

1) Protocol number and title, name of PI of record, supervisor name and contact information, and names and contact information for all associate investigators.
2) A clear explanation of the reason for administrative hold rather than project closure or transfer to a new PI and what actions, if any are needed, are being taken to protect the rights and welfare of the research subjects.
3) A clear explanation of the plan and timeline for assignment of a new PI or return of the PI of record that, if applicable, includes time for the new PI to complete required training and familiarize themselves with the USMC HRPP Policy and Procedures and other applicable policies.
4) A checklist of required records indicating where each item currently is located and how the responsible vice chair or IRB Chair can gain access.
5) An explanation of where project data are located and how the responsible vice chair or IRB Chair can gain access.
6) A list of other research materials that include subjects' personal information indicating where each item currently is located and how the responsible vice chair or IRB Chair can gain access.

The IRB Chair shall make a determination on whether to allow administrative hold within 15 business days after receiving a complete request. If administrative hold will be allowed, the IRB Chair shall establish the initial duration of the hold and coordinate subsequent actions with the organization's vice chair or organizational point of contact.

If an amendment appointing a new PI or notice that the PI of record has resumed duties is not received 15 business days prior to the end of the established hold period, the IRB Chair may begin the process of closing the protocol or may coordinate with the organization to determine an appropriate course of action.

The IRB Chair, in consultation with vice chairs and the IRB membership, may reduce or extend the administrative hold timeline, require additional information, or take other actions as needed for specific cases.

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25 Records Retention

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Both the PI and IRB have responsibilities for retaining records associated with human subjects research (HSR) protocols. The IRB also has responsibility for maintaining records of IRB membership and activities. Additionally, the USMC HRPP has responsibility for maintaining records associated with its DON assurance.

This chapter addresses records retention for PIs, the USMC IRB, and the USMC HRPP to ensure compliance with DON and DoD policies related to HSR and reference (b). It does not address other records retention requirements that may be directed by broader USMC, DON, and DoD records policies.

For the purposes of this policy, the phrase "protected information" refers to information that the protocol and informed consent agreement state will be protected from disclosure outside the IRB-approved research team, authorized HRPP staff, and USMC IRB vice chairs and members. What constitutes protected information is dictated by the details of each specific protocol. Protected information often, but not always, includes information considered Personally Identifiable Information (PII) under DoD policy. However, some protocols may not protect PII and/or may protect other types of information.

25.1 PI Responsibilities

1) **Basic requirements**. In accordance with reference (b), the PI shall retain the records listed in the USMC HRPP PI Records Retention Checklist (Appendix I) for a period of at least three years after the date of project closure (per date on IRB approval of Final Report or Termination). Primary records must be digital. Signed informed consent documents and other records containing protected information may be retained in paper form if digitization is not consistent with the protections described in the informed consent document and protocol. At the end of the three-year period records may be destroyed if no longer needed for reference unless longer retention is required under reference (d) or unless other local organizational record-keeping requirements apply.

2) **Protected information**. The PI shall ensure that records including protected information, such as signed informed consent documents, are stored in a way that limits access to only IRB-approved members of the research team. (Staff of the USMC and DON HRPPs also may require access to these records for routine monitoring or other purposes, but access can be provided on an as-needed basis.) The PI shall ensure the destruction of all paper and digital copies of protected information or redaction of protected information from records when no longer needed for reference and no longer required under this policy, reference (d), or local organizational policies.

    a. If local record-keeping requirements conflict with the need for secure storage and destruction or redaction of records containing protected information, the PI shall consult with the IRB Chair to resolve the conflict in a way that maintains the protections provided to subjects under the protocol and informed consent agreement.
    b. Records including protected information shall not be transferred to organizational records systems, repositories, or to any physical or digital storage outside the PI's or IRB's control without written permission of the USMC IRB.

3) **Alternative storage options**. If the PI is unable to provide appropriate storage or plans to leave their organization before the required storage timeline has elapsed, they shall contact their organizational vice chair or the IRB Chair to arrange for records to be transferred to an IRB-approved records repository.

4) **Data**. There is no requirement for the PI to retain project data. However, if the protocol and informed consent agreements allow for future use and/or sharing of data, PIs are encouraged to explore options for long-term storage, such as data repositories. Data storage and sharing must be consistent with the protections promised to subjects in the protocol and informed consent agreements. PIs are encouraged to consult with the IRB before selecting a long-term storage option or entering into a sharing agreement.

25.2 USMC IRB Responsibilities

1) **Basic requirements**. The IRB shall retain the records listed in the "IRB File" column of the USMC HRPP Records Retention Checklist (Appendix H) in accordance with reference (m). Records shall be digital. The IRB also shall transmit records to DON HRPP as indicated in the checklist. As of the date of this policy, to comply with reference (m) the IRB shall:

    a. After protocol closure, establish a cutoff date at the end of the calendar year.
    b. 30 years after the cutoff date, transfer records to the National Archives and Records Administration (NARA).

2) **Sensitive records**. Protocol records occasionally may include personally identifiable information (PII) of subjects, e.g., in records associated with unanticipated problems or adverse events or in correspondence to the IRB from subjects. The IRB Administrator or IRB Chair shall ensure that personally identifiable information (PII) of subjects is redacted/removed prior to transfer to NARA.

3) **IRB Membership and Operations**. The IRB shall maintain records of its membership and operations as indicated in the USMC HRPP Records Retention Checklist (Appendix H). The retention period for these records is permanent. Permanent retention may be accomplished within the program or by transfer to an appropriate repository as dictated by service policies.

25.3 USMC HRPP Responsibilities

1) **Assurance Records**. The USMC HRPP shall maintain records associated with its assurance including initial assurance, assurance updates, and assurance renewals. The retention period for these records is permanent. Permanent retention may be accomplished within the program or by transfer to an appropriate repository as dictated by service policies.

2) **Records of USMC HRPP Appointments**. The USMC HRPP shall maintain all records of appointments to USMC HRPP roles other than IRB appointments (e.g., Human Protections Director, Human Research Protection Official, or IO). The retention period for these records is permanent. Permanent retention may be accomplished within the program or by transfer to an appropriate repository as dictated by service policies.

3) **USMC IRB Records**. The USMC HRPP shall manage the maintenance and transfer of all required records associated with the USMC IRB.

25.4 Records Retention Monitoring

The USMC IRB and the USMC HRPP may conduct periodic inspections of PI, IRB, and HRPP records, including both open and closed protocols, as needed to ensure compliance.

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(a) Title 10, United States Code, Section 980, Limitation on Use of Humans as Experimental Subjects

(b) Title 32, Code of Federal Regulations Part 219, Protection of Human Subjects

(c) Title 45, Code of Federal Regulations Part 46, subparts B, C, and D, Protection of Human Subjects

(d) DoD Instruction 3216.02 (Series), Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research

(e) SECNAVINST 3900.39 (Series), Human Research Protection Program

(f) The Belmont Report, 44 Federal Register Page 23192 of 18 April 1979

(g) SECDEF Memo, 13 December 1999, Interim Policy for Protection of Human Subjects in Classified Research

(h) Revised Common Rule published in the Federal Register / Vol. 82, No. 12 / Thursday, January 19, 2017 / Rules and Regulations

(i) DoD Directive 5230.09, Clearance of DoD Information for Public Release

(j) SECNAVINST 5720.44B, Public Affairs Policy

(k) DoD Directive 2310.01E, DoD Enemy Prisoner of War Detainees Program

(l) OPNAVINST 5300.8C, Coordination and Control of Personnel Surveys

(m) SECNAV M-5210.1, Records Management Manual

(n) DoD Instruction 3210.7, Research Integrity and Misconduct

(o) Title 21, Code of Federal Regulations Food and Drugs Chapter I - Food and Drugs Administration, Department of Health and Human Services, Sub Chapter A, Part 56, Institutional Review Boards

(p) Title 21, Code of Federal Regulations, Food and Drugs Chapter I - Food and Drugs Administration, Department of Health and Human Services, Sub Chapter A, Part 50 Protection of Human Subjects

(q) Title 5, U. S. Code Section 3109, Employment of Experts and Consultants; Temporary and Interim.

(r) 48 CFR 207.172, 235.072(e), and DFARS Clause 252.235-7004 Protection of Human Subjects

(s) Section 30 of Title 24, U.S.C. Payments to donors of blood for persons undergoing treatment at Government expense

(t) MCO 3900.18, Human Research Protections Program

(u) MCO 5300.18 USMC Survey Order

(v) E.O. 13526 Classified National Security Information

(w) DODI 5230.29 - Security and Policy Review of DoD Information for Public Release

(x) DoDI 3200.12 DoD Scientific and Technical Information Program (STIP) 2013 (17 Dec 2018)

(y) Office of Science and Technology Policy Memorandum for the Heads of Executive Departments and Agencies: Ensuring Free, Immediate, and Equitable Access to Federally Funded Research. 25 August 2022

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Appendix A: Categories of Exemption

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Excerpts from 32 CFR 219.104, Protection of Human Subjects, Section 104 (d):

"Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

Exempt Category (1): Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exempt Category (2): Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

> (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
> (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
> (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §219.111(a)(7).

Exempt Category (3):

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

> (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
> (B) Any disclosure of the subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
> (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers

linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §219.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Exempt Category (4): Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i)The identifiable private information or identifiable biospecimens are publicly available;

(ii)Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501. Note if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Exempt Category (5): Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to

those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

Exempt Category (6): Taste and food quality evaluation and consumer acceptance studies:

(i)If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempt Category (7): Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential **secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §219.111(a)(8).**

Exempt Category (8): Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §219.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §219.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §219.111(a)(7) that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv), the investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

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Appendix B: Expedited Review Categories

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Expedited Review Category 1. Clinical studies of drugs and medical devices when either condition (a) or (b) is met.

a. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs in which the research exposure would significantly increase the risks or decrease the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b. Research on medical devices for which either:

1. an investigational new device exemption application is not required; or
2. the medical device is cleared / approved for marketing and the medical device is being used in accordance with its cleared / approved labeling.

Expedited Review Category 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture according to the restrictions in the applicable category:

a. *Healthy non-pregnant adults who weigh at least 110 pounds.* For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period, and the collection may not occur more frequently than two times per week.

b. Other adults. Considering the age, weight, and health of the subjects, the collection procedure, the amount of blood collected, the frequency with which it will be collected, the amount drawn may not exceed the lesser of 50 ml or 3 ml / kg in an 8-week period, and collection may not occur more frequently than two times per week.

Expedited Review Category 3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include hair and nail clippings collected in a non-disfiguring manner; deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; permanent teeth if routine care indicates a need for extraction: excreta and external secretions (including sweat); uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane prior to or during delivery; supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and sputum collected after saline mist nebulization.

Expedited Review Category 4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays, microwaves, or potentially injurious directed energy such as lasers. When medical devices are employed, they must be cleared or approved for marketing. (Note: Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples of activities that may be eligible for expedited review include:

a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the

subject's privacy;
b. Weighing and testing sensory acuity;
c. Magnetic resonance imaging;
d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;
e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Expedited Review Category 5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes, such as medical treatment or diagnosis.

Expedited Review Category 6. Collection of data from voice, video, digital, or image recordings made for research purposes.

Expedited Review Category 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies.

Expedited Review Category 8. Continuing review of greater than minimal risk research that was previously approved by the convened IRB may be conducted using expedited review procedures if it falls into any one of the following categories:

a. Where all three of the following conditions are met:

(1) The research is permanently closed to the enrollment of new subjects; and

(2) All subjects have completed all research-related interventions; and

(3) The research remains active only for long-term follow-up of subjects.

b. Where no subjects have yet been enrolled and no additional risks have been identified since IRB review; or

c. Where all remaining research activities are limited to data analysis.

Expedited Review Category 9. Continuing review of approved minimal risk research may be conducted using expedited review procedures when the research was originally reviewed by the convened IRB only because it did not fit into categories 2 through 7, as long as:

a. the research was not conducted under an investigational new drug application or investigational device exemption; and

b. no additional risks have been identified since the convened IRB review.

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Appendix C: Abbreviations, Acronyms, and Initialisms

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BLS	Basic Life Support
CFR	Code of Federal Regulations
CITI	Collaborative Institutional Training Initiative
COI	Conflict of Interest
CR	Continuing Review
CRADA	Cooperative Research and Development Agreement
DoD	Department of Defense
DON	Department of Navy
FDA	Food and Drug Administration
FRC	Federal Record Center
FWA	Federalwide Assurance
HQ	Headquarters
HRP	Human Research Protection
HRPO	Human Research Protection Official
HRPP	Human Research Protection Program
HSR	Human subjects research

IAIR	Institutional Agreement for IRB Review
IIA	Individual Investigator Agreement
IO	Institutional Official
IPA	Intergovernmental Personnel Act
IRB	Institutional Review Board
NCO	Non-Commissioned Officer
PI	Principal Investigator, Research Personnel
SBIR	Small Business Innovative Research
SECDEF	Secretary of Defense
SG	Surgeon General
SOP	Standard Operating Procedure
SOW	Statement of Work
UPIRTSO	Unanticipated Problem Involving Risk to Subjects or Others

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Appendix D: Definitions

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Note on business days and timelines. Where possible in this policy, business days rather than calendar days, weeks, and months are used for clarity except where higher-level guidance applies and is not specific regarding the use of business or calendar periods. Except when otherwise noted, years are calendar years.

A business day is any day, Monday through Friday, that is not designated as a holiday by the Office of Personnel Management. If notified by the PI, the IRB Chair or Administrator also may make adjust the business day calculation to account for days when the PI's primary work location was officially closed (due to weather conditions or for other reasons) or other disruptions outside the PI's control.

The following timeline equivalencies are used:

Calendar Period	**Business Days**
1 week	5 business days
6 weeks	30 business days
1 month	20 business days
3 months	60 business days

Adverse Event. An adverse event is any untoward or unfavorable occurrence associated with the conduct of a research project, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms. For Food and Drug Administration (FDA)-regulated research, the definition of adverse event should be followed.

USMC HRPP Administrative Review. A review of a research protocol and supporting documents (e.g., safety review, scientific review, IRB approval) related to USMC supported or assisted research involving human subjects which ensures the institution engaged in the research involving human subjects has met the requirements of all applicable regulations and policies, to include USMC HRPP policies. This includes all non-USMC conducted research that requests access to service members or federal employees of the Marine Corps as potential subjects or access to personal data about those individuals. This review is NOT an IRB review.

Approval Authority for Research Protocols. Individuals with delegated approval authority that permit research to begin. Such individuals also have authority to certify a research protocol.

Assistance. See USMC-Assisted Research.

Associate Investigator. Associate investigators assist the principal investigator with the design and conduct of a research project or task. Associate investigators are "engaged" in HSR. (See engaged)

Assurance. See Institutional Assurance.

Assurance Approval Authority. Individuals authorized to approve and renew institutional assurances to DON activities and extramural performers conducting HSR, and the authority to accept other DoD or Federal Assurances.

Business Day. See "Note on business days and timelines" at start of Definitions section.

Certification. The official notification by the institution to the supporting federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Classified Research Involving Human Subjects. Research involving human subjects where the protocol or other information required by the IRB for review and oversight, or required or provided by the research subjects includes classified information, as defined in reference (v).

Collaborator. See Extramural Performer.

Common Rule. The regulation adopted by multiple federal departments and agencies for the protection of human subjects in research. The DoD's implementation of the Common Rule is 32 Code of Federal Regulations (CFR) part 219 (32 CFR 19); the Department of Health and Human Services' implementation of the Common Rule is subpart A of 45 CFR part 46.

Conflict of interest. Any situation in which professional, financial, or personal interests may compromise or present the appearance of compromising an individual's or group's judgment in conducting, reviewing, approving, managing, and supporting research.

Continuing Non-compliance. A pattern of non-compliance (see non-compliance) that suggests the likelihood that, without intervention, instances of non-compliance will recur, a repeated unwillingness to comply with this policy and procedures, or a persistent lack of knowledge of how to comply with the references or this USMC HRPP Policy and Procedures.

DoD-affiliated Personnel. Service members, Reserve Service members, National Guard members, DoD civilians, and DoD contractors. (Note that this definition is for the purposes of assessing the applicability of certain policies only, such as those regarding compensation. For other purposes, such as research collaboration or inclusion as subjects, contractors are not considered DoD personnel. See details in applicable chapters of this policy.)

DoD Personnel. DoD civilian employees and members of the Military Services. USMC and DON personnel are subsets of DoD personnel.

a. **DoD Civilian Employee**. An individual meeting the definition of "employee" consistent with section 2105 of Title 5, U.S.C. It includes employees of DoD Non-Appropriated Fund Instrumentalities; DoD civilian employees filling full-time, part-time, intermittent, or on- call positions; and individuals serving under personal services contracts consistent with section 2.101 of Title 48, U.S.C. It excludes employees of contractors (other than personal services contractors) and

foreign nationals of host countries.

b. **Service Members**. Individuals appointed, enlisted or inducted for military service under the authority of the DoD. The Military Services are the Army, the Navy, the Air Force, the Marine Corps, the Coast Guard in some circumstances, and the Reserve Components, which includes the Army and the Air National Guards of the United States. Members of the Reserve Components are included when in a duty status.

Engaged in Research. An institution is engaged in research involving human subjects when its personnel are conducting activities covered by section 219.101(a) of reference (b) and this policy and procedures. An institution that is funding, providing equipment, providing access to or information about potential human subjects (but not recruiting human subjects), providing data or specimens (either identifiable or not) or overseeing the research from a regulatory or compliance standpoint is not engaged in the research involving human subjects but is supporting or assisting the research (see "USMC supported" or "USMC assisted" research involving human subjects.")

Exempt Research Involving Human Subjects. Research involving human subjects where the only involvement of the human subjects in the research will be in one or more of the categories identified in section 219.104 of reference (b).

Exemption Determination Official (EDO). Serves as a local HRPP official designated by the IO for the purposes of reviewing the institution's proposed activities with humans and making official determinations regarding whether an activity (1) is research involving human subjects, (2) meets exemption criteria per reference (b), section 219.104 or (3) is research involving human subjects that requires IRB review. EDOs must be federal employees or service members who are sufficiently qualified through training or experience to be able to ascertain the acceptability of a proposed activity, while being sufficiently removed from the activity to avoid the appearance of a conflict of interest.

Extramural Performer. Any individual or organization outside of the DoD that is a party to a contract, grant, interagency transfer, or other agreement with any Navy or Marine Corps activity or who is proposing to conduct research involving Marine Corps personnel, data, facilities, or other resources. An organization includes any federal, state, municipal, or other government activity, or any corporation, institution, foundation, agency, or other legal entity, whether foreign or domestic.

Greater Than Minimal Risk. Greater Than Minimal Risk research is defined as any research using human subjects that does not meet the criteria as Minimal Risk.

Headquarters-Level Administrative Review. Administrative review of approved research protocols by DON HRPP to verify regulatory compliance and human research protections following local approval.

Human Subject. A living individual about whom an investigator (whether

professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the

subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

Identifiable private information. Identifiable private information is private information based on which the identity of the subject may readily be ascertained by the investigator or associated with the information. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

Institution. Any public or private entity, or department or agency (including federal, state, and other agencies).

Institutional Assurance. A document originated by an institution and granted by an Assurance Approval Authority authorizing the institution to engage in research supported by the DoD stating that it will comply with federal regulations, DoD, and DON requirements for human subjects protections.

Institutional Review Board. The IRB is a committee established in accordance with reference

(b) to review research to ensure the protection of the rights and welfare of human research subjects.

Institutional Review Board Member—Naval / Marine Corps (DON) IRBs. A DON IRB member must be a current federal employee, an individual appointed under the Intergovernmental Personnel Act (IPA), or a consultant consistent with the requirements established by reference (q) (5 USC 3109). Status as a contractor or federal retiree alone is not sufficient to qualify as a federal employee for the purpose of IRB membership.

Institutional Official. An institution's senior person who is legally authorized to represent the institution and who is authorized to establish and is responsible to maintain the HRPP for the institution. The IO is responsible for the institution's DoD or Federal Assurance and IRB, if these elements are part of the institution's HRPP. The IO assumes, on behalf of the institution, the obligations imposed by the federal regulations, DoD, and DON requirements for the protection of human subjects. The IRB chair and IRB members may not serve as the IO.

Intervention and Interaction. An intervention includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between the investigator and subjects. See section 219.102(e) of reference

(b) for more information. Examples include, but are not limited to, a physical procedure, a drug, a manipulation of the human subject's environment, the withholding of an intervention that would have been undertaken if not for the research purpose, or communication such as a survey or interview.

Investigational Test Articles. Drugs, biologicals, and devices defined by U.S. Food and Drug Administration (FDA) as "investigational" because they are not yet approved for public use or commercial distribution. See also "Test Article."

Minimal Risk. The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The phrase "ordinarily

encountered in daily life or during the performance of routine physical or physiological examinations or tests" in the definition of minimal risk shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain) (reference (d) Paragraph 6.b).

Misconduct. See Research Misconduct

Naval Activities. Refers to both Navy and Marine Corps activities.

Non-compliance. Failure of a person, group or institution to act in accordance with the USMC HRPP Policy and Procedures, its references, or applicable requirements.

Ombudsperson. A person who acts as an impartial and objective advocate for human subjects participating in research. The ombudsperson is assigned by the IRB chair, when necessary, for research involving greater than minimal risk and also involving military members, or federal employees of the DoD, when recruitment occurs in a group setting. During recruitment briefings to a unit where a percentage of the unit is being recruited to participate as a group, an ombudsperson not connected in any way with the proposed research or the unit from which volunteers are being recruited, shall be present to monitor that the voluntary nature of individual participants is clearly and adequately stressed and that the information provided about the research is clear, adequate and accurate. The ombudsperson ensures no superiors of the potential participants are present during the recruitment and Informed Consent process. The ombudsperson reports recruitment compliance to the IRB chair.

Principal Investigator (PI). The Principal Investigator (PI) is the researcher who has the primary responsibility for the design and conduct of a research project or task. In USMC-conducted HSR, the PI must be a current service member assigned to the USMC or a USMC civilian employee who possesses the required education, knowledge, skills, experience (credentials) to initiate, conduct and oversee HSR, and has completed the required research ethics training including human subjects protections.

Prisoner. Any individual (other than Captured or Detained Personnel) involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal, civil or military statute, individuals detained in other facilities by virtue of statutes or commitment procedures, which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial or sentencing. [Reference (c), 45 CFR 46.303(c)]

Protected Information. For the purposes of this policy, the term "protected information" refers to information that the protocol and informed consent agreement state will be protected from disclosure outside the IRB-approved research team, authorized HRPP staff, and USMC IRB vice chairs and members. What constitutes protected information is dictated by the details of each specific protocol. Protected information often, but not always, includes information considered PII under DoD policy. However, some protocols may not protect PII and/or may protect other types of information.

Protocol. The detailed written research plan. A document that describes the background, rationale, objectives, design, methodology, and organization of a research investigation. In HSR,

the protocol is frequently synonymous with the application for approval of a research study to an IRB.

Research. Any activity that is a systematic investigation, including Research, Development, Testing, and Evaluation (RDT&E), designed to develop or contribute to generalizable knowledge as defined in section 219.102(d) of reference (b). This includes activities where the results are intended for publication, distribution, or use outside of the Marine Corps, or where the results are to be used in future research activities. Activities that meet this definition constitute research for purposes of this policy whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. [Reference (b), 32 CFR 219.102(d)]

1) Research includes, but is not limited to, any project, task, test, pilot study, experiment, investigation, study, clinical study, clinical investigation, clinical trial, evaluation, developmental effort or similar undertaking, whether or not conducted or supported under a program that is officially considered research. Any effort, even if not considered research for other purposes, is considered research for purposes of this policy and associated procedures.

2) Clarification of FDA-regulated Research: The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous. Clinical investigation means any experiment that involves a test article and one or more human subjects, and meets the appropriate requirements for prior submission to the Food and Drug Administration. [Excerpted from reference (o) (21 CFR 56.101(c)) and reference (p) (21 CFR 50.3(c))]

Research Involving Human Subjects. Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual

about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information. Activities covered by section 219.101(a) of reference (b) (including exempt research involving human subjects) and this policy and associated procedures. The following activities conducted or supported by the DoD are NOT research involving human subjects:

1) Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs of the DoD, including health surveillance per reference (e) and the use of medical products per reference (f).

2) Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment.

3) Activities performed for the sole purpose of medical quality assurance consistent with section 1102 of Title 10, U.S.C. and reference (h).

4) Activities performed solely for an OT&E project where the activities and project meet the definition of OT&E as defined in section 139(a)(2)(A) of Title 10, U.S.C.

5) Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational

health and safety reviews, network monitoring and monitoring for compliance with requirements for protection of classified information.

6) Activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program.

7) Survey, interview, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by reference (j).

Research Misconduct. Defined in reference (n) as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion."

Risk. The possibility of harm, discomfort, or injury (physical, psychological, sociological, economic, or other) as a consequence of any act or omission resulting from participation in a research study. Risk can range from minimal to high. Determination of the nature and degree of risk involved in a research project must be determined by the IRB chair or IRB, not the PI, even if the project is deemed to be "Minimal Risk."

Serious Adverse Event. Adverse events with serious effect or potential for serious effect, whether or not the event was expected to occur during the research.

Serious Noncompliance. Failure of a person, group, or institution to act in accordance with the USMC HRPP Policy and Procedures and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

Service Members. See DoD Personnel.

Test Article. Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act. [Reference (o) (21 CFR 56.102(1)) and reference (p) (21 CFR 50.3(j))]

Supported Research. See USMC Supported Research.

USMC-Assisted Research Involving Human Subjects. Research involving human subjects for which the USMC is providing non-financial resources to non-DoD institutions/researchers who are not using DoD funding, including, but not limited to, facilities, equipment, access to information about DoD-affiliated personnel for recruitment, or access to DoD-affiliated personnel, data, or specimens. An example of USMC-Assisted Research is a scholarly project by a student or faculty member from a civilian university who is not being funded by the DoD.

USMC-Conducted Research Involving Human Subjects. Research involving human subjects that is performed by USMC personnel and reviewed and approved by the USMC IRB. USMC-conducted research is one type of DON supported research involving human subjects. See "engaged in research involving human subjects." Research is considered USMC-Conducted whenever the PI is a service-member assigned to the USMC or a government civilian employee

of the Marine Corps and the USMC IRB is the reviewing IRB even if non-USMC personnel work on the project under IIAs or other collaborative agreement.

USMC-Supported Research Involving Human Subjects. Research involving human subjects for which the USMC is providing at least some of the resources (see "research involving human subjects"). Resources may include, but are not limited to funding, facilities, equipment, personnel (investigators or other personnel performing tasks identified in the research protocol), access to or information about USMC personnel for recruitment or identifiable data or specimens from those individuals. It includes both USMC-conducted research involving human subjects and research involving human subjects conducted by a non-USMC institution.

Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO). Any incident, experience, or outcome that meets ALL three of the following conditions:

1) Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.
2) Is related or possibly related to participation in the research (in this policy and associated procedures, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
3) Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

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Appendix E: USMC HRPP Post-Approval Monitoring (PAM)

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In accordance with reference (d), the USMC HRPP conducts post-approval monitoring (PAM) of human subjects research carried out under its oversight. PAM activities are conducted by the USMC IRB Chair, USMC IRB Administrator, and, when designated by the USMC IRB Chair, USMC IRB vice chairs and members. PAM focuses on ensuring that research conducted under the oversight of the USMC IRB is conducted in compliance with applicable regulations and policies and in the best interest of subjects.

The USMC IRB will conduct PAM on at least two protocols in the USMC IRB portfolio each year. If the portfolio exceeds 100 protocols, the USMC IRB will conduct PAM on at least 10% of its portfolio. For the purposes of the count, the USMC HRPP may include PAM conducted by other assured institutions that rely on the USMC IRB. However, not all of the protocols audited in a given year may come from other assured institutions.

The USMC HRPP may choose to conduct PAM activities for any open protocol in the USMC IRB's portfolio. Selection does not necessarily indicate that there are concerns about the investigators or research conduct or records. The purpose of PAM activities is to ensure that the consent process, research activities, data management, and records retention are being conducted in accordance with the IRB-approved protocol, requirements of the IRB, and applicable regulations.

When a protocol is chosen for PAM, the IRB Chair, IRB Administrator, or designee will review the complete protocol file and assign an appropriate individual to conduct monitoring activities in one of the two categories below.

Whenever practical, the PAM category including direct observation shall be used. PAM without direct observation shall be used only when it is not possible to send a qualified monitor to the research site(s), when doing so is not in the best interests of the subjects, when all research subjects' recruitment and participation does not involve direct contact with the research team (e.g., an online survey), or when data gathering is not ongoing.

1) Post-Approval Monitoring Including Direct Observation. The individual assigned to conduct PAM activities shall:
    a. Review the complete protocol file.
    b. Contact the PI and indicate the activities to be observed, required discussions, and the frequency and duration of the observations and establish mutually agreeable times and dates.
    c. At a minimum, observe the consent process (if applicable to the protocol). Based on the review of the protocol file and guidance from the IRB chair, the assigned individual also may choose to include any or all of the following:
        i. Observation of research conduct.
        ii. Tour of facilities used to conduct research and analysis.
        iii. Inspection of data and record storage systems.
        iv. Observation of research team meetings.

v. Meeting with PI's supervisor.

vi. Other activities as appropriate based on the details of the protocol.

d. Audit signed informed consent forms (if applicable to the project) and verify eligibility of subjects enrolled.

i. Note that this may be accomplished via other records or discussion with the PI if project documentation does not include retaining sufficient data on each subject to verify eligibility.

ii. For projects with a large number of enrolled subjects, a sample may be used to verify eligibility.

e. Verify that enrollment numbers adhere to the approved protocol.

f. Through observation and/or discussions with the research team, verify that the approved protocol is being followed.

i. Note that this may include verifying that information protected under the protocol is stored appropriately and that measures to protect the information (e.g., destruction of code keys) and de-identify data are followed in accordance with the procedures and timeline in the protocol.

g. Through observation and/or discussions with the research team, verify that only approved personnel are conducting research activities on the protocol.

h. Through observation and/or discussions with the research team, verify that unanticipated problems and serious adverse events were reported.

i. Through observation and/or discussions with the research team, verify that modifications to the protocol were approved prior to implementation.

j. Verify that required documentation for all research personnel is on file with the IRB and up to date.

k. Verify that required records are maintained.

l. Provide the PI, other research team members, and, if applicable, the PI's supervisor with an opportunity to ask questions and provide feedback to the IRB.

m. Document the PAM as indicated in this appendix.

2) Post-Approval Monitoring Without Direct Observation. The individual assigned to conduct PAM activities shall:

a. Review the complete protocol file.

b. Contact the PI and indicate the required discussions and establish mutually agreeable times and dates.

c. At a minimum, conduct an in-depth discussion with the PI and any Associate Investigators in which they detail the consent process (if applicable to the protocol). Based on the review of the protocol file and guidance from the IRB chair, the assigned individual also may choose to include any or all of the

following:

i. A discussion of facilities used to conduct research and analysis.

ii. Virtual inspection of data and record storage systems.

iii. Virtual observation of research team meetings.

iv. Meeting with PI's supervisor.

v. Other activities as appropriate based on the details of the protocol.

d. Audit signed informed consent forms (if applicable to the project) and verify eligibility of subjects enrolled.

i. Note that this may be accomplished via other records or discussion with the PI if project documentation does not include retaining sufficient data on each subject to verify eligibility.

ii. For projects with a large number of enrolled subjects, a sample may be used to verify eligibility.

e. Verify that enrollment numbers adhere to the approved protocol.

f. Through in-depth discussions with the research team, verify that the approved protocol is being followed.

i. Note that this may include verifying that information protected under the protocol is stored appropriately and that measures to protect the information (e.g., destruction of code keys) and de-identify data are followed in accordance with the procedures and timeline in the protocol.

g. Through discussions with the research team, verify that only approved personnel are conducting research activities on the protocol.

h. Through discussions with the research team, verify that unanticipated problems and serious adverse events were reported.

i. Through discussions with the research team, verify that modifications to the protocol were approved prior to implementation.

j. Verify that required documentation for all research personnel is on file with the IRB and up to date.

k. Verify that required records are maintained.

l. Provide the PI, other research team members, and, if applicable, the PI's supervisor with an opportunity to ask questions and provide feedback to the IRB.

m. Document the PAM as indicated in this appendix.

3) Documentation of PAM.

a. If evidence of previously unknown/unreported serious or continuing non-compliance, research misconduct, serious adverse event, or UPIRTSO was found, the individual conducting PAM shall notify the IRB chair by telephone or email immediately (within one business day).

b. Individuals assigned to conduct PAM activities shall document their findings using a template provided by the USMC HRPP or another format approved by the USMC IRB Chair.

c. Documentation shall include a description the type of PAM (with or without direct observation), the protocol number and title, the names, titles, and contact information of the PI and the PI's supervisor, the date(s) and location(s) of the PAM, and a list of who was in attendance at PAM events, along with:

   i. The assigned individual's assessment of all items listed in the appropriate PAM category in this appendix.

   ii. The assigned individual's assessment of the research team's adherence to applicable USMC, DON, and DoD policies and procedures.

   iii. A list of required actions for the PI and/or the PI's supervisor or a statement that no actions are required.

   iv. A list of recommended actions for the PI and/or the PI's supervisor or a statement that no actions are recommended.

   v. A description of questions and feedback provided by the research team and/or the PI's supervisor, along with an explanation of how these were addressed during the meeting and whether any follow-up communication is needed.

   vi. If evidence of previously unknown/unreported serious or continuing non-compliance, research misconduct, serious adverse event, or UPIRTSO was found, a description of the issue(s) and recommendation(s) to the IRB chair regarding follow-up activities.

d. The individual conducting the PAM activities shall provide documentation to the IRB chair within 10 business days of completing the PAM activities. After review by the IRB chair and any necessary revisions, the IRB chair or IRB Administrator shall ensure that a copy is placed in the protocol's permanent records and shall provide copies of documentation to:

   i. The PI and the PI's supervisor.

   ii. The IRB prior to the next convened meeting.

   iii. DON HRPP if evidence of previously unknown/unreported serious or continuing non-compliance, research misconduct, serious adverse event, or UPIRTSO was found.

4) PI Right to Appeal PAM Findings. A PI who disagrees with some or all of the findings in PAM documentation may appeal. Appeals may take different forms, such as requesting that clarifications or corrections be added to the document or requesting that the PAM activities be conducted again with a different individual assigned.

   a. A PI seeking to appeal PAM findings may do so by contacting the IRB chair. If the PI has concerns about the IRB chair's ability to fairly manage the appeal, they may make their appeal to the USMC IO. PIs also may request to present their appeal to the convened IRB.

b. All requests for appeal must be made in writing within 60 calendar days of delivery of the PAM report.

c. The USMC HRPP shall accommodate all appeal requests in a timely manner. However, the USMC HRPP is not required to address the appeal in the manner suggested by the PI. For example, if a PI requests that PAM be re-conducted by a different person, the USMC HRPP may instead allow the PI and the person who conducted the PAM to brief the USMC IRB and arrange for the IRB to vote on whether another PAM is warranted.

d. In cases where the USMC IRB is required to vote on a PAM appeal, the IRB's decision shall be final.

5) Feedback Integration. The IRB chair and IRB Administrator shall ensure that feedback from PIs, other research team members, and supervisors is integrated into USMC HRPP and USMC IRB materials and operations as appropriate. The IRB chair shall ensure that the IRB has the opportunity to discuss or vote on changes when appropriate. Integration may include changes in the content or format of routine communication with PIs, creation or revision of informational materials, revision of application materials, changes to the USMC HRPP Policy and Procedures, or other actions.

6) Relationship Between PAM and Investigations. While PAM and investigations into allegations of issues in the conduct of research are related, they are distinct activities. Investigations are initiated by the IRB when there is reason to believe that there has been or currently is serious or continuing non-compliance, research misconduct, a serious adverse event, or a UPIRTSO. The majority of PAM activities are routine and not linked to concerns about the protocol or research team. However, PAM activities may uncover issues that lead to an investigation. Also, PAM activities may be used as part of an investigation or as part of necessary corrective actions identified during an investigation.

7) USMC HRPP Support to Other Marine Corps Assured Institutions. Other Marine Corps Institutions, having their own IAs, and supported by the USMC IRB under Institutional Agreements for IRB Review, have post-approval monitoring plans as required by their IAs. The USMC IRB Chair and USMC HRPP staff may be available to assist other institutions in post-approval monitoring upon request.

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Appendix F: Waivers of Consent and Waivers of Documentation of Consent

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WAIVER OR ALTERATION OF INFORMED CONSENT. As outlined in reference (b), General Requirements for Informed Consent, a waiver or alteration of consent is authorized if it meets the criteria outlined below. Reference (b) should be consulted for more detailed information about waivers and alterations of consent.

In order for an IRB to waive or alter consent as described in reference (b), 32 CFR §219.116(f), the IRB must find and document that:

1) The research is exempt or is non-exempt and involves no more than minimal risk to the subjects;
2) The research could not practicably be carried out without the requested waiver or alteration;
3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

WAIVER OF THE REQUIREMENT FOR DOCUMENTATION OF CONSENT. As described in reference (b), 32 CFR §219.117(c), an IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

1) That the research is exempt under reference (b).
2) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
3) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
    a. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
    b. In cases in which the documentation requirement is waived, the IRB may require

the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

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Appendix G: Process for Delegation of Authorities and Responsibilities

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In the event that a member of the USMC HRPP staff will be absent or unable to attend to duties for a period of time long enough to compromise the ability of the USMC HRPP to operate effectively or to address time sensitive issues that arise during a shorter absence period, authorities and responsibilities may be delegated by the USMC HRPP Director/IRB Chair (actual only) or by the USMC IO as described below unless delegation is prohibited by higher-level guidance.

1) USMC IRB Chair duties may be delegated to a USMC IRB vice chair who may then serve temporarily in an acting capacity. Delegation of these responsibilities beyond the conduct of a single IRB meeting requires approval of the USMC IO.
2) USMC IRB Administrator duties may be delegated to a USMC IRB vice chair or other federal employee who has completed the appropriate training.
3) Authority to conduct Administrative Reviews may be delegated to a USMC IRB vice chair or to a HRPO in any of the service's HRPPs.
4) Authority to conduct expedited reviews may be delegated to a USMC IRB vice chair.
5) EDO and HRPO duties may not be delegated. Performance of these duties requires that the individual be appointed to the role by an IO and submission of an assurance update to DON HRPP. EDOs and HRPOs from M&RA and Systems Command who have been cross-appointed to the USMC institutional assurance may perform EDO and HRPO duties for the USMC HRPP.

Responsibilities shall not be delegated without the agreement of the individual who will serve in an acting capacity and that person's supervisor.

Formal appointment letters are not required. Delegation may be accomplished via email.

The USMC IRB Administrator or USMC IRB Chair (acting or actual) will notify the full USMC IRB of any delegation of IRB chair or IRB administrator authorities and responsibilities within five business days of the delegation. Notification to DON HRPP is not required.

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Appendix H USMC HRPP Records Retention Checklist

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USMC IRB – Required PI and IRB Records	PI File (3 years)	IRB File (per ref m)	IRB submits to DON HRPP
Initial Review of New Protocol			
Document granting approval to start research			
Statement of supervisor support for research (IRB Action Request)			**N/A**
Scientific or scholarly review (if applicable to protocol)			
Approved research protocol with number and date			
The following data/information gathering instruments if applicable to the protocol			
• Survey instruments, interview/focus group questions, or similar documentation of the questions that subjects will be asked to answer. (For projects using semi- or un-structured methods, a sample of questions may be included.)			
• Testing instruments			
• Data collection forms			
• Recruiting, advertising materials, notification letters			
• Enrollment and screening questionnaires			
• Subject information sheets			
• (For projects using existing datasets) Description of data sources and list of data fields to be used			
The following consent, permission, and assent documents if applicable to the protocol. These are blank, unsigned versions of the documents showing the IRB approval stamp and, if applicable, expiration date. In cases where the documents are re-issued with new IRB approval stamps and/or expiration dates, a copy of each version should be retained in the protocol's records.			
• Informed consent document and/or script			
• IRB approved Photographic Release or other permissions			
• Parental permission form if using children as subjects			
• Child assent if using children as subjects			
Documentation of other reviews when applicable to the protocol			
• Safety, Other			
• Survey program approval (when applicable, usually obtained after IRB approval)		**N/A**	**N/A**
Documentation of Commanding Officer Support			
Documentation of Flag Officer Support if applicable			
Documents supporting collaboration (approval documents from collaborating institutions) if applicable			
Agreements supporting research (IAIR, MOU, MOA, CRADA, etc.) if applicable			
Research Personnel			
The information below must be retained for all personnel approved to work on the project from initial review through project closure. This documentation may be retained as part of records of initial review and amendments to the protocol or separately.			
Name, title, and contact information of the PI			
Names and titles of all associate investigators and research support personnel with role in the research project indicated for each.			

USMC IRB – Required PI and IRB Records	PI File (3 years)	IRB File (per ref m)	IRB submits to DON HRPP
Human subjects research education and training documentation for PI, associate investigators, and research support personnel (typically CITI certificates)			**N/A**
CVs, bios, or other documentation of qualifications for the PI and associate investigators			**N/A**
Signed Investigator Affirmation(s)			
Signed Investigator Conflict of Interest Statement(s)			
Signed Individual Investigator Agreement(s) (if applicable)			
Continuing Review Report/Progress Report Submission(s)			
Continuing Review Report(s) or Progress Report(s) and associated materials			
Document approving continuous research			
Amendment/Modification Submission			
Amendments to the protocol and/or Informed Consent			
Document approving amendment			
Unanticipated Problem/Adverse Event Submission			
Submission Form and associated documentation			
Document with results of IRB Review			
Statement of Significant New Findings			
Documents informing subjects			
Suspension/Re-instatement			
IRB/Command Review of Suspension			
Document Suspending Research			
Document Reinstating Research			
Document Terminating Research			
Final Report Submission			
Project Final Report			
Document Approving Final Report			
Project Withdrawal Notification, if applicable			
Document Acknowledging Withdrawal, if applicable			
Other Protocol Records			
Any publications, briefings, etc. based on protocol			**N/A**
Significant official correspondence associated with the protocol			**N/A**
Results of investigations of allegations of non-compliance or research misconduct (sent to DON HRPP if required by policy)			
Reports from post-approval monitoring.			
Other documentation as directed by IRB			
Original (or digital scan of original) signed consent documents for all subjects unless the requirement for consent or documentation of consent was waived by the IRB		**N/A**	**N/A**
Original (or digital scan of original) signed parental permission, child asset, and other subject-related agreement forms, if applicable to protocol		**N/A**	**N/A**
Other IRB Records (Permanent)			
IRB Meeting Agendas	**N/A**		
IRB Meeting Attendance Lists	**N/A**		
IRB Meeting Minutes	**N/A**		
Significant official IRB correspondence (retain in accordance with correspondence standards in reference m)	**N/A**		**N/A**
Policies and procedures for IRB operations	**N/A**		

USMC IRB – Required PI and IRB Records	PI File (3 years)	IRB File (per ref m)	IRB submits to DON HRPP
List of IRB members including information required under reference (b).[1] Submit to DON HRPP and maintain records as part of assurance updates.	**N/A**		
Documentation of Appointments to the IRB (chair, vice chairs, Members) Submit to DON HRPP and maintain records as part of assurance updates.	**N/A**		

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[1] Name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant.

Appendix I USMC HRPP Principal Investigator Records Retention Checklist

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Principal Investigators (PI) of all human subjects research projects conducted under USMC IRB oversight shall retain the records listed below (as applicable to the protocol) for three years after protocol closure unless longer retention is required under DoDI 3216.02 and its references or due to local records policies. In accordance with the USMC HRPP Policy and Procedures, PIs who will leave their institution or are unable to provide appropriate storage of records must arrange for transfer of records to the USMC IRB or their organizational vice chair's IRB-approved records repository.

Note: If a protocol's records include signed consent documents, other materials that could be used to identify subjects, or other information protected under the protocol, these materials **shall** be protected as described in the informed consent agreement and protocol.

PIs **shall not** transfer such records to organizational records systems, repositories, or to any physical or digital storage outside the PI's or IRB's control without written permission of the USMC IRB.

USMC IRB – Required PI Records	**PI File**
Initial Review of New Protocol	
Document granting approval to start research	
Statement of supervisor support for research (IRB Action Request)	
Scientific or scholarly review (if applicable to protocol)	
Approved research protocol with number and date	
The following data/information gathering instruments if applicable to the protocol	
Survey instruments, interview/focus group questions, or similar documentation of the questions that subjects will be asked to answer. (For projects using semi- or un-structured methods, a sample of questions may be included.)	
• Testing instruments	
• Data collection forms	
• Recruiting, advertising materials, notification letters	
• Enrollment and screening questionnaires	
• Subject information sheets	
• For projects using existing datasets) Description of data sources and list of data fields to be used	
The following consent, permission, and assent documents if applicable to the protocol. These are blank, unsigned versions of the documents showing the IRB approval stamp and, if applicable, expiration date. In cases where the documents are re-issued with new IRB approval stamps and/or expiration dates, a copy of each version should be retained in the protocol's records.	
• Informed consent document and/or script	
• IRB approved Photographic Release or other permissions	
• Parental permission form if using children as subjects	
• Child assent if using children as subjects	
Documentation of other reviews when applicable to the protocol	
• Safety, Other	
• Survey program approval (when applicable, usually obtained after IRB approval)	
Documentation of Commanding Officer Support	
Documentation of Flag Officer Support if applicable	
Documents supporting collaboration (approval documents from collaborating institutions) if applicable	
Agreements supporting research (IAIR, MOU, MOA, CRADA, etc.) if applicable	
Research Personnel	

USMC IRB – Required PI Records	PI File
The information below must be retained for all personnel approved to work on the project from initial review through project closure. This documentation may be retained as part of records of initial review and amendments to the protocol or separately.	
Name, title, and contact information of the PI	
Names and titles of all associate investigators and research support personnel with role in the research project indicated for each.	
Human subjects research education and training documentation for PI, associate investigators, and research support personnel (typically CITI certificates)	
CVs, bios, or other documentation of qualifications for the PI and associate investigators	
Signed Investigator Affirmation(s)	
Signed Investigator Conflict of Interest Statement(s)	
Signed Individual Investigator Agreement(s) (if applicable)	
Continuing Review Report/Progress Report Submission(s)	
Continuing Review Report(s) or Progress Report(s) and associated materials	
Document approving continuous research	
Amendment/Modification Submission	
Amendments to the protocol and/or Informed Consent	
Document approving amendment	
Unanticipated Problem/Adverse Event Submission	
Submission Form and associated documentation	
Document with results of IRB Review	
Statement of Significant New Findings	
Documents informing subjects	
Suspension/Re-instatement	
IRB/Command Review of Suspension	
Document Suspending Research	
Document Reinstating Research	
Document Terminating Research	
Final Report Submission	
Project Final Report	
Document Approving Final Report	
Project Withdrawal Notification, if applicable	
Document Acknowledging Withdrawal, if applicable	
Other Protocol Records	
Any publications, briefings, etc. based on protocol	
Significant official correspondence associated with the protocol	
Results of IRB investigations of allegations of non-compliance or research misconduct	
Reports from post-approval monitoring of the protocol by the IRB	
Other documentation as directed by IRB	
Original (or digital scan of original) signed consent documents for all subjects unless the requirement for consent or documentation of consent was waived by the IRB	
Original (or digital scan of original) signed parental permission, child asset, and other subject-related agreement forms, if applicable to protocol	

Data are not included in the records required by the USMC HRPP. However, PIs are encouraged to consider consult with the USMC HRPP regarding options for data repositories.

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Appendix J Data Projects, Data Requests, and Data Sharing Agreements

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Scope of this guidance

This guidance applies to all projects involving the use of existing data about USMC personnel, including:

1. all projects reviewed by the USMC IRB.
2. external projects that are reviewed by another IRB and are subject to Administrative Review or HRPO Review by the USMC HRPP.
3. human subjects research.
4. projects that have received a "not human subjects research" (not HSR) determination from an IRB.

The M&RA HRPP or MCSC HRPP may place additional requirements or restrictions on projects that originate in or are funded by their organizations or that are requesting data from their organizations.

Introduction

As with other types of projects, PIs and leads for projects that will involve the use of data about USMC personnel are responsible for ensuring that they comply with applicable policies regarding required reviews and the conduct of their projects.

USMC IRB and USMC HRPP reviews address the types of data to be requested, plans for use, plans for storage, security, and disposal, and, if applicable, de-identification processes. The reviews also address the potential risks to USMC personnel whose data will be used. Reviews focus on mitigating or removing risks to USMC personnel, compliance with applicable laws and policies, and, for projects that are human subjects research, scientific soundness.

The USMC IRB and USMC HRPP cannot direct data holders to release data and do not facilitate interactions between researchers and data holders.

Note: In the guidance below, the term "reviewing IRB" refers to the IRB that approved the protocol or issued a "not HSR" determination. In many cases, this will be the USMC IRB. However, external researchers and project leads may have used their own institution's IRB or a private company that provides IRB services.

PI/project lead initial responsibilities

The PI or project lead is responsible for:

- ensuring review and approval (or a "not HSR" determination) by the appropriate IRB.
- identifying points of contact for data sources, submitting data requests, establishing data agreements with the data holders.
- ensuring that data holders are aware of the scope and limitations of the approved protocol or, if the project is not HSR, project description.
- ensuring that requests and agreements conform to the approved protocol or project description.

- providing the reviewing IRB (and, if applicable, USMC HRPP) with copies of finalized data requests and data sharing agreements.
- notifying the reviewing IRB of any potential changes to determine if an amendment or re-review is required.

PIs and project leads are encouraged to coordinate with data holders prior to finalizing and submitting their materials to their reviewing IRB to ensure that the intended data are available and can be provided as expected.

Changes to HSR data projects

Negotiations with data holders may result in changes. For example, a protocol may specify that de-identified data will be requested for a limited number of data fields, but the data holder may be unable to de-identify the data or may need to provide a greater number of data fields because of how the data source is structured. Before receiving the data, the PI must report these changes to the reviewing IRB and determine if an amendment is required. Only the reviewing IRB is authorized to make this decision. For protocols by external researchers that have undergone HRPO or Administrative Review by the USMC HRPP, the PI also must notify the USMC HRPP to determine if review of the change is required.

Protocols sometimes need to evolve as researchers learn more about the data and their topic. Before requesting additional data from the same source or a different source, the PI must notify reviewing IRB and determine if an amendment is required. Only the reviewing IRB is authorized to make this decision. For protocols by external researchers that have undergone HRPO or Administrative Review by the USMC HRPP, the PI also must notify the USMC HRPP to determine if review of the change is required.

Changes to data projects that are not NHSR

Changes to the data that will be requested or received and additional data requests may alter the IRB's determination that a project is not HSR. For example, receipt of identified rather than deidentified data or adding certain data fields could result in a different determination. Any changes or additions to your data plans must be reported to your reviewing IRB. Only the reviewing IRB is authorized to determine whether the changes will necessitate a second review. For protocols by external researchers that have undergone HRPO or Administrative Review by the USMC HRPP, the PI also must notify the USMC HRPP to determine if review of the change is required.

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Appendix K USMC HRPP Appointment and Relief Processes for HRPOs, EDOs, IRB Chair, IRB Vice Chairs, and IRB Members and Alternates

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The USMC IO appoints and relieves individuals to / from all roles within the USMC HRPP (see Chapters 4, 5, and 6). The administrative aspects of the appointment and relief processes described below may be changed as needed for specific circumstances as long as the substantive aspects of the appointment are consistent with applicable references. Options for and limitations on delegation of authorities associated with HRPO, EDO, and IRB chair roles are addressed in Appendix G.

The USMC IO shall ensure that DON HRPP is notified of appointments and reliefs in accordance with this policy and its references.

Appointment

HRPOs

The USMC IO selects individuals falling under the USMC HRPP assurance to serve as HRPOs. Typically, these individuals are employees of the USMC HRPP, but other individuals may be selected with the concurrence of the individual's command. After verifying the individual's qualifications and HRPO-specific training, the IO ensures that the appointment package is forwarded to the individual and DON HRPP and is entered in the USMC HRPP's records.

The appointment package consists of the individual's documentation of qualification and training and a document or email from the IO confirming appointment. It also may include direction to the appointed individual regarding the responsibilities of the role or these may be communicated separately.

The USMC IO ensures that HRPO's training is up to date as part of the annual assessment of the program.

EDOs

The USMC IO selects individuals falling under the USMC HRPP assurance to serve as EDOs. Typically, these individuals are employees of the USMC HRPP, but other individuals may be selected with the concurrence of the individual's command. After verifying the individual's qualifications and EDO-specific training, the IO ensures that the appointment package is forwarded to the individual and DON HRPP and is entered in the USMC HRPP's records.

The appointment package consists of the individual's documentation of qualification and training and a document or email from the IO confirming appointment. It also may include direction to the appointed individual regarding the responsibilities of the role or these may be communicated separately.

The USMC IO ensures that EDO's training is up to date as part of the annual assessment of the program.

IRB Chair

The USMC IO selects an individual falling under the USMC HRPP assurance to serve as the USMC IRB Chair. Typically, the individual is an employee of the USMC HRPP, but other individuals may be selected with the concurrence of the individual's command. After verifying the individual's qualifications and IRB chair-specific training, the IO ensures that the appointment package is forwarded to the individual and DON HRPP and is entered in the USMC HRPP's records.

The appointment package consists of the individual's documentation of qualification and training and a document or email from the IO confirming appointment. It also may include direction to the appointed individual regarding the responsibilities of the role or these may be communicated separately.

The USMC IO ensures that the USMC IRB Chair's training is up to date as part of the annual assessment of the program.

IRB Vice Chairs and Members

Commands falling under the USMC HRPP assurance or relying on the USMC HRPP for IRB services may nominate an individual to serve as IRB vice chairs or members based on a request from the USMC IRB or independently. The USMC IRB also will request an IRB member from one or more unaffiliated organizations to meet membership requirements.

Nomination must be made by the senior military officer or civilian in the individual's command. The nomination may be made by letter, form, or email, but must be accompanied by documentation of the nominee's qualifications and role-appropriate training. The nominating organization must be able to support the individual to perform the duties of the role for which they are being nominated.

The USMC IO may reject nominations based on the needs of the board in terms of overall numbers, organizational representation, or expertise mix or based on assessment of the nominee's qualifications. However, if a nomination is rejected, the rationale shall be provided in a letter or email to the nominating command.

If the nomination is accepted, after verifying the individual's qualifications and appropriate IRB training, the IO ensures that the appointment package is forwarded to the individual and DON HRPP and is entered in the USMC HRPP's records.

The appointment package consists of the individual's documentation of qualification and training, a copy of the letter or email nominating the individual, and a document or email from the IO confirming appointment. It also may include direction to the appointed individual regarding the responsibilities of the role or these may be communicated separately.

The USMC IO ensures that IRB vice chair and member training is up to date as part of the annual assessment of the program.

Alternates

The process for the nomination and appointment of alternate vice chairs and alternate members is

the same as for primary vice chairs and members with the following exception.

During the appointment process, the USMC IO and USMC IRB Chair will establish the conditions under which an alternate may act as an alternate for another vice chair or member. Conditions may include acting as an alternate for a primary vice chair or member

- in the same organization (if paired with a primary member)
- with the same categorization as a scientist or non-scientist
- with the same categorization as an unaffiliated member
- with related expertise.

The conditions under which the individual may be authorized to act as an alternate must be documented in the appointment package.

Relief

Administrative

The USMC IO may relieve an individual due to changes in employment or assignment status or, when applicable, at the request of the individual's command. No formal relief package is required. The individual and, if applicable, their command may be notified by letter, form, or email.

Substantive

See Chapter 9 regarding removal of the USMC IRB Chair.

The USMC IO may relieve an EDO or HRPO within the USMC HRPP based on assessment of the individual's performance in the role or workload considerations. The individual may be notified verbally, in writing, or via email.

The USMC IO, with concurrence of the USMC IRB Chair, may relieve a vice chair, member, or alternate from the IRB based on assessment of the individual's performance. Factors considered may include the individual's:

- demonstrated understanding of the principals and policies associated with IRB decisions,
- responsiveness and attendance,
- behavior during board activities,
- behavior with other board members, USMC HRPP staff, and investigators.

Except in unusual circumstances, this will be done only after consultation with the individual and the individual's command to attempt to address any issues. The individual and their command may be notified in writing or via email.

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