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WASHINGTON, DC 20350-3000

MCO 3900.18
CD&I (C06)
21 Jan 2011

MARINE CORPS ORDER 3900.18

From: Commandant of the Marine Corps
To: Distribution List

Subj: HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

Ref: (a) SECNAVINST 3900.39D
(b) Federal Register, Volume 44, Belmont Report, 23192, April 18, 1979
(c) DOD Directive 3216.02, "Protection of Human Subjects And Adherence to Ethical Standards in DOD-Supported Research," March 25, 2002
(d) 32 CFR 219
(e) Defense Federal Acquisition Regulation Supplement (DFARS) 207.172, 235.072, & 252.235-7004
(f) 10 U.S.C. 980
(g) DON HRPP Education Policy of 9 Jan 2007
(h) SECNAV M-5210.1
(i) 5 U.S.C. 3109
(j) 45 CFR 46
(k) 21 CFR 56
(l) 21 CFR 50
(m) 42 U.S.C. 1

Encl: (1) Amplifying Guidance
(2) Reporting Non-compliance, Misconduct, Serious Adverse Events, Unanticipated Problems
(3) Human Research Protection Official (HRPO)
(4) Abbreviations, Acronyms, and Definitions

1. Situation. To establish policy and assign responsibility for the protection of human subjects in research conducted by, within, or for the U.S. Marine Corps in accordance with reference (a) through (m).

2. Mission

a. The protection of the rights and welfare of research subjects is an acknowledged and accepted Service responsibility. This Marine Corps Order details specific procedures to ensure

the protection of human subjects. Constructive communication and dialog among all parties involved in the review and conduct of research involving human subjects is required as a means of maintaining an awareness of the importance of safeguarding the rights and welfare of human subjects.

b. The U.S. Marine Corps uses the ethical principles below as the foundation for its human research, per reference (b).

(1) Respect for Persons. Respect for persons incorporates at least two ethical convictions: first, individuals should be treated as autonomous and provided protection; and second, persons with diminished autonomy are entitled to a heightened level of protection.

(a) Informed consent is an application of the general principle of respect for persons. As stated in reference (a), voluntary informed consent is fundamental to ethical research with humans. Informed consent cannot be obtained simply by reading or signing a document; it is a process that begins with subject recruitment. Informed consent includes a thorough discussion with prospective subjects and/or their legally authorized representatives and continues for at least the duration of the research.

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

(2) Beneficence. Beneficence, in research meets two general rules: first, do not harm; and second, maximize possible benefits and minimize possible harms.

(3) Justice. Justice requires that people are treated fairly. Subjects must be selected equitably, and vulnerable populations and populations of convenience must be provided additional protections.

3. Execution

a. Commander's Intent and Concept of Operations

(1) Commander's Intent. Ensure research activities involving people, whether Marines or otherwise, are conducted in a manner that respects the individual, is beneficent, and just.

(2) Concept of Operations

(a) The Secretary of the Navy delegated the authority and responsibility for the Department of the Navy Human Research Protection Program (HRPP) to the Navy Surgeon General (SG), except for those specifically retained by the Secretary of the Navy and those delegated to the Under Secretary of the Navy.

(b) The Navy SG may delegate to Commanders, Commanding Officers, and Officers in Charge the authority to approve human subjects research protocols under their respective cognizance through an approved DOD-Navy Assurance for the Protection of Human Research Subjects.

(c) Commanders, Commanding Officers, Officers in Charge and Heads of Activity may delegate to Institutional Review Board (IRB) Chairs and Vice Chairs the authority to review and make recommendations for research that 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. This authority may not be further delegated.

(d) The Deputy Commandant for Combat Development and Integration (DC, CD&I) serves as the coordinating authority for the HRPP within the Marine Corps. Marine Corps IRBs will be established to review and evaluate research protocols.

(3) Marine Corps Commanders, Commanding Officers, Officers in Charge or Heads of Activity will forward all requests for human subject research to an IRB for review and approval. The reviewing IRB may be any IRB established in accordance with reference (d).

(4) Tasks

(a) DC, CD&I. Act as Marine Corps coordinator for the HRPP with responsibility for oversight of Marine Corps human research protections.

(b) Executive Deputy, Training and Education Command (TECOM). As the Marine Corps Combat Development Command (MCCDC) Institutional Official (IO), establish, operate, and maintain the MCCDC command-level human research protection program to support human subject research requirements for MCCDC and its subordinate commands. The appointment of an HRPP IRB Administrator/Human Research Protection Official (HRPO) for MCCDC is authorized. The MCCDC HRPP IRB Administrator/HRPO shall be the initial point of contact for questions and guidance regarding HRPP matters.

(c) Commanding General, Marine Corps Systems Command (CG MARCORSYSCOM). Establish, operate, and maintain command-level human research protection program to support human subject research requirements within MARCORSYSCOM while providing HRPP related assistance to Marine Corps Operational Test and Evaluation Activity (MCOTEA) and other acquisition related activities in the Marine Corps as required. Additionally the appointment of a HRPO in accordance with enclosure (3) may be necessary.

(d) Headquarters Marine Corps (Health Service) will provide support, expertise, and coordination between the Navy SG; Bureau of Medicine and Surgery (BUMED); Office of Naval Research (ONR); and DC, CD&I as required.

(e) All Marine Corps Commanders, Commanding Officers, Officers in Charge or Heads of Activity shall:

1. Comply with and support the requirements for human research protection as directed in this Order and references (a) through (f), to include obtaining HRPP Assurance from the Navy SG, as required.

2. Establish procedures to ensure all research involving humans (social, behavioral and educational), and all operational test and evaluation research that is supported, sponsored, performed, conducted, or authorized in the Command, is reviewed by an appropriate IRB, and when required, approved by an HRPP IO.

3. Forward requests for conducting human research to an established IRB. Marine Corps organizations can request review from IRBs outside the Marine Corps.

4. Obtain written approval from the appropriate research approval authority prior to conducting, continuing, or implementing changes to human subject research protocols.

5. Notify DC, CD&I immediately when reporting Non-compliance, Misconduct, Serious Adverse Events, or Unanticipated Problems in accordance with reference (a).

(f) Coordinating Instructions

1. Education and Training. All personnel involved in reviewing, approving, supporting, conducting, managing, or overseeing research involving human subjects research must complete initial and ongoing research ethics and human subject protections training appropriate to each

individual's level of involvement, duties, and responsibilities. This includes but is not limited to the IO, all IRB members, all HRPOs, all Principal Investigators, associate investigators, and support personnel directly involved in research. This also includes personnel selected as local command advisors to research teams. DON HRPP provides training through a web-based program available to all Navy and Marine Corps commands. Commands must supplement this training to meet their unique requirements.

2. Authority to terminate or suspend previously approved human subject research is delegated to IOs, designated IRBs, IRB chairs, and IRB vice-chairs. Once terminated or suspended, review by a convened IRB and re-approval by the appropriate IO is required.

3. References (c) and (f) place additional protections and limitations on all potential subjects including active and reserve component military members and DOD civilians. Due to the attractiveness of military members as research subjects, they are often the targets of graduate student theses, dissertation studies, and other non-DOD researchers. Compliance with references (a) through (f) must be considered when granting student access to military populations.

4. Reference (e) requires the designation and identification of a HRPO who is responsible for the oversight and execution of the requirements of HRPP in acquisition planning.

5. Enclosures (1) through (4) are provided for amplification.

4. Administration and Logistics. To ensure government accountability and protect the rights of the individuals and the Federal government in the event of an allegation of research misconduct, records are to be managed as permanent records until the passage of time determines an appropriate disposition as a permanent or temporary record. All records are to be managed as permanent records according to N1-NU-05-1, SSIC 3900.5a and/or 3900.9, with review to occur as records near the end of their lifecycle as a potential temporary record, i.e., when 30 years old per reference (h).

5. Command and Signal

a. Command. This Order is applicable to the Marine Corps Total Force.

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

GEORGE J. FLYNN
Deputy Commandant for
Combat Development and Integration

DISTRIBUTION: PCN 10203614000

Amplifying Guidance

To facilitate initial understanding, this enclosure re-states key elements of information from the references. It is not intended to be all inclusive. The references should be used for more accurate information and complete understanding. For additional information about the HRPP, the MCCDC IRB Administrator may be contacted.

The vast preponderance of actions that constitute human research will generally occur within a command that conducts testing and/or evaluation, such as MCCDC and MARCORSYSCOM. However, in some rare instances, activities involving humans may fall within the requirements of reference (a). In such cases, the commander of the unit in question shall seek review by the MCCDC IRB Administrator or local staff judge advocate prior to conducting the activity in question whether the activity is the conduct of a survey or actual physical/mental testing of human beings.

1. Assurance Requirement. Human subjects research covered by this Order 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 IRB to review research protocols, and the institution's plan for monitoring its human subjects research. Human subjects research 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 granted by an appropriate research approval authority.

2. Human Participant versus Human Subject. Human subjects research is defined in reference (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 human subjects research. Human participation requires safety involvement to ensure the safety of participants, but may not require involvement of the IRB for human subject's protection. The determination whether or not a research activity requires review by an IRB will be made by an authorized IRB chair/vice chair or an individual duly authorized and trained to make such determinations. Determinations made to not forward for IRB review will be made in writing and

maintained by the approving authority for at least one year after the completion of the study.

3. Conflicting Regulations. Issues pertaining to the protection of human subjects are constantly evolving, and there may at times be conflicts between applicable regulations. 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 DON HRPP.

4. 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 may require permission of the host country. The laws, customs, and practices of the host country and those required by this Order will be followed.

5. Classified Research. Classified research with human subjects is held to the same ethical principles and human subject protections as unclassified research and must receive prior approval from the Secretary of Defense (SECDEF). Classified research is not eligible for review under expedited review procedures.

6. Public Release of Research Information. To foster public trust in research and human subject protections, information may be made available to the public, the news media, and Congress. This information may be released after appropriate review and approval.

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

8. Compensation. Civilians and military personnel not in a duty status (e.g., normal off duty hours, reservists not on active duty, etc.) 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.

9. 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 (a), (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 active duty personnel. Regardless of the risk level of the research, no seniors shall influence the decisions of their subordinates whether to participate as research subjects.

10. 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.

Reporting Non-Compliance, Misconduct, Serious Adverse Events, Unanticipated Problems

1. Allegations of non-compliance with Human Subject Protections. All participants, researchers, or support personnel shall be informed of their right to report concerns of non-compliance to the PI, IRB Chair, or IRB Vice-Chair immediately. The IO shall review all allegations of non-compliance with human subject protections and take action, if appropriate and report the initiation of all investigations and report results regardless of the findings to the Navy SG and appropriate sponsors.

2. Allegations of Research Misconduct. All participants, researchers, or support personnel shall be informed of their right to report concerns of misconduct to the PI, IRB Chair, or IRB Vice-Chair immediately. The IO shall review all allegations of research misconduct and take action if appropriate and report the initiation of all investigations and report results regardless of the findings to the Navy SG and appropriate sponsors. Notify DC, CD&I concurrently any time a report is made alleging Non-compliance, Misconduct, Serious Adverse Events or Unanticipated Problems.

Human Research Protection Official(HRPO)

Commands seeking to fund human subject research shall appoint a government employee or employees as the Command HRPO. Because most commands are unlikely to sponsor a large enough volume of research involving human subjects to warrant a full-time HRPO, the position generally will be a collateral or additional duty. Qualified candidates may be selected from any of several command positions. For example, the HRPO could be an individual assigned to the legal (although not encouraged), program management, headquarters, financial management, or command HRPP office. A Contracts Office staff member also could be considered, but the HRPO could not be the same Contracting Officer awarding the contract under HRPO review.

- The HRPO is responsible for oversight and execution of the Command's Human Research Protection Program, and for compliance with all DON and DOD human research protection policies. Commands must implement a HRPO process that ensures adherence to regulatory requirements.

- The HRPO is responsible for verifying that human subject research protection documentation is appropriate for the research to be performed. This review must be conducted prior to the award of research involving human subjects.

- The HRPO must complete and document initial and continuing research ethics and human subject protections training. Review specific training requirements with DON HRPP or a Marine Corps IRB HRPP Point of Contact for additional information

Abbrieviations, Acronyms And Definitions

Abbreviations/Acronyms

BUMED	...	Bureau of Medicine and Surgery
CFR	...	Code of Federal Regulations
FDA	...	Food and Drug Administration
HRPO	...	Human Research Protection Official
HRPP	...	Human Research Protection Program
IO	...	Institutional Official
IPA	...	Intergovernmental Personnel Act
IRB	...	Institutional Review Board
ONR	...	Office of Naval Research
PI	...	Principal Investigator, Research Personnel
SG	...	Surgeon General
VCNR	...	Vice Chief of Naval Research

Definitions

Adverse Event. Any unfavorable and unintended occurrence associated with the conduct of a research project.

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

Associate Investigator. Associate investigators assist the researcher with the design and conduct of a research project or task.

Assurance. See Institutional Assurance.

Assurance Approval Authority. Individuals authorized to approve and renew institutional assurances to DON activities and extramural performers conducting human subjects research, and the authority to accept other DOD or federal assurances.

Certification. The official written notification by the performing institution that a research project or activity involving human subjects has been reviewed and approved by an IRB per an approved assurance. [Reference (d),102(j)]

Collaborator. Any individual or organization within or outside the Marine Corps that is engaged in and works together (partners) with Marines to conduct research. See Extramural Performer.

Engaged in Research. An activity becomes engaged in research when its personnel or agents either intervene or interact with living individuals for research purposes; or obtains individually identifiable private information for research purposes.

Extramural Performer. Any individual or organization that is a party to a contract, grant, interagency transfer, or other agreement with any Navy or Marine Corps activity. 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 exceeds the criteria for 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 conducting research obtains either data through intervention or interaction with the individual or identifiable private information. Intervention includes both physical procedures by which data 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 investigator and subject. Identifiable private information is any information from which the identity of the subject associated with the collected data is or may be readily ascertained by the investigator or associated with the institution. Private information also 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.

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 subject protections.

Institutional Review Board. The IRB is a committee established in accordance with reference (d), to review research to ensure the protection of the rights and welfare of human research subjects.

Institutional Review Board Member—Naval 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 (i). 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. A senior leader (the Commander, Commanding Officer, Officer in Charge or Head of Activity) authorized to act for the institution and to assume 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.

Intramural Performer. Any Department of the Navy command, activity, or organization, including MCCDC, MARCORSYSCOM or PEO LS personnel that engage in research involving human subjects.

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.

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

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 DON-supported human subject research, the PI must currently be a federal employee who possesses the required education, knowledge, skills, experience (credentials) to initiate, conduct and oversee human subject research, and has completed the required research ethics training including human subject protections.

The requirements for both DON-supported Intramural Research and DON-supported Extramural Research are outlined in reference (a).

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 (j), 303(c)]

Protocol. The detailed written research plan.

Research. Any systematic investigation to include a project, task, test, experiment, development, demonstration, evaluation, or similar undertaking designed to develop or contribute to generalized knowledge. This includes activities where the results are intended for publication, distribution, or use outside of MCCDC, MARCORSYSCOM, PEO LS or where the results are to be used in future research activities. Activities that meet this definition constitute research for purposes of this instruction 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 (c) and (d), 102(d)] 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 instruction. 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 (k), 101(c) and reference (l), 3(c)]

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."

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 reference (m). [References (k), 102(1) and (l), 3(j)]