DEPARTMENT OF THE NAVY
OFFICE OF THE SECRETARY
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WASHINGTON DC 20350-1000

SECNAVINST 3900.39D
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SECNAV INSTRUCTION 3900.39D

From: Secretary of the Navy

Subj: HUMAN RESEARCH PROTECTION PROGRAM

Ref: (a) DoD Directive 3216.2, Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research," 25 Mar 2002
(b) Title 32, Code of Federal Regulations 219
(c) DoD Directive 6200.2, "Use of Investigational New Drugs for Force Health Protection," 1 Aug 2000
(d) The Belmont Report, 44 Federal Register 23192 of April 18, 1979
(e) Title 10, United States Code, Section 980
(f) Title 45, Code of Federal Regulations 46
(g) DoD Directive 2310.01E, "DoD Enemy Prisoner of War Detainees Program," 18 Aug 1994 (under revision)
(h) OPNAVINST 5300.8B of 19 May 05
(i) Title 21, Code of Federal Regulations 50
(j) Title 21, Code of Federal Regulations 56
(k) Title 21, Code of Federal Regulations 312
(l) Title 21, Code of Federal Regulations 812
(m) Title 21, Code of Federal Regulations 600
(n) Title 63, Federal Register 60364-60367 of 9 Nov 98
(o) Title 42, Code of Federal Regulations 93
(p) DoD Instruction 3210.7, "Research Integrity and Misconduct," 14 May 2004
(q) DoD Directive 5230.9, "Clearance of DoD Information for Public Release," 9 Apr 1996
(r) SECNAVINST 5720.44B of 1 Nov 05
(s) SECNAV M-5210.1 of 1 Dec 05
(t) Title 5, United States Code, Section 3109
(u) SECNAV M-5214.1 of 1 Dec 05

Encl: (1) Definitions

1. Purpose. To establish policy and assign responsibility for the protection of human subjects in research conducted by, within, or for the Department of the Navy (DON) per reference (a). This instruction has been extensively rewritten and should be read in its entirety.

2. Cancellation. SECNAVINST 3900.39C.

3. Background

a. The DON supports human subject research to develop, test, and evaluate warfighting systems, casualty-care and personnel protection systems, clothing, and devices, and vaccines and drugs for disease prevention and treatment. Human subject research is essential to protect the health and optimize the performance of Sailors and Marines. Research involving human subjects receives considerable national and international attention. Support from all echelons is required to maintain the highest standards of research conduct and to provide for the ethical treatment and well-being of human research subjects.

b. Research as defined in reference (b) is a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes." See enclosure (1) for a more detailed definition.

4. Scope

a. This instruction applies to:

(1) All biomedical and social-behavioral research involving human subjects conducted by Navy and Marine Corps activities or personnel, involving naval military personnel and DON employees as research subjects, or supported by naval activities through any agreement (e.g., contract, grant, cooperative agreement, or other arrangement), regardless of the source of funding, funding appropriation, nature of support, performance site, or security classification. It also applies to human subject research using DON property, facilities, or assets.

(2) Human subject research conducted in the development, testing or evaluation of any item, system, vehicle, aircraft, piece of equipment, or other materiel, even if a person is not the direct object of the research. Examples include training exercises associated with the testing of personal protective equipment when worn by a person or the study of a new clinical laboratory test requiring freshly drawn or stored blood.

(3) Human subject research that meets criteria for exemption as defined in reference (b) and as determined by Institutional Review Board (IRB) Chairs, IRB Vice Chairs, designated IRB administrators, or designated officials of the DON Human Research Protection Program (HRPP). Investigators shall not make this determination.

(4) Individuals, for example, test pilots and experimental divers, who are specifically qualified by training and experience to perform hazardous duties who become subjects in research, regardless of whether the research is collateral or unrelated to their assignments.

b. This instruction does not apply to:

(1) Activities that do not qualify as research or activities that do not involve human subjects as defined in reference (b) and as determined by IRB Chairs, IRB Vice Chairs, designated IRB administrators, or designated officials of the HRPP. Investigators shall not make this determination.

(2) Individuals or organizations that perform commercial services, provide products, or perform other services without professional recognition or publication privileges.

(3) Investigators or research staff installing, familiarizing themselves with, or calibrating research equipment in preparation for the research effort, prior to IRB review unless the data collected during those preparatory efforts will be used in the research.

(4) Research using cadavers. However, institutions proposing to support or conduct this research shall meet requirements for scientific merit, comply with applicable state laws regulating organ donation for science or research, and verify that the research is limited to cadavers. If the research involves direct connections, coded connections, or other links of private identifiable information between deceased and living individuals, then an ethics review by an IRB is required.

(5) The use of investigational drugs, biological products, or devices for the purposes of Force Health Protection. Such use is governed by reference (c).

c. The requirements in this instruction shall not be suspended or waived due to operational contingency or during times of national emergency, except by explicit action of the Secretary of the Navy.

d. Nothing in this instruction is intended to supersede either the requirements for health or safety reviews required by other authority, or to limit the authority of health care practitioners to provide emergency medical care to the extent individuals are permitted to do so under applicable federal, state, or local law.

5. Definitions. See enclosure (1).

6. Policy

a. Guiding Principles. The DON uses the ethical principles outlined in the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (reference (d)), as the foundation for its human research protection program.

(1) Respect for Persons. The rights, welfare, interests, privacy, confidentiality, and safety of human subjects shall be held paramount at all times and all research projects shall be conducted in a manner that avoids all unnecessary physical or mental discomfort, and economic, social, or cultural harm.

(2) Education and Training. All personnel involved in reviewing, approving, supporting, conducting, managing, or overseeing research involving human subjects must complete initial and ongoing research ethics and human subject protections training appropriate to each individual's level of involvement, duties, and responsibilities. In addition, education and training for investigational agent use for Force Health Protection is required by reference (c).

(3) Informed Consent. Voluntary informed consent is fundamental to ethical research with humans. Informed consent is not simply 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. 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 (e).

(4) Command Responsibility. All Navy and Marine Corps personnel conducting, supporting, reviewing, approving or managing human research 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, 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.

(a) Human subject 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 IRB, and approved by an appropriate research approval authority.

(b) A Department of Defense (DoD) Navy Assurance is a document originated by the institution engaged in human subject research that states that it will comply with federal, DoD, and DON requirements for human subject protections. The DoD Navy Assurance is reviewed and approved by the Surgeon General of the Navy (Navy SG). Key requirements of the DoD Navy Assurance are completion of research ethics training, designation of IRB(s) to review research protocols, and the institution's plan for monitoring its human research.

(c) Approval of research is required prior to recruiting subjects, enrolling subjects, collecting data or specimens, analyzing data, conducting research interventions, or preparing publications or presentations. The institution performing the research also must meet all the requirements of this instruction.

(5) Research-related Injury. Due to the possibility of injuries arising from participation in human subject research, every project involving greater than minimal risk shall include an arrangement for emergency treatment and necessary follow-up of any research-related injury. IRBs will determine whether research involving minimal risk also might include a similar arrangement for research-related injury.

(6) 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) and (f) require additional safeguards for children, 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. Regardless of the risk level of the research, no superiors (civilian supervisors, officers, and noncommissioned officers (NCOs)) shall influence the decisions of their subordinates (e.g., junior enlisted personnel) whether to participate as research subjects.

(7) Chemical-Biological Research. Research involving testing of chemical or biological agents shall comply with reference (a).

(8) Captured or Detained Personnel. Research involving any person captured, detained, held, or otherwise under the control of DoD personnel (military and civilian, or contractor employee) 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. See references (a) and (g).

b. Conflict of Interest. Conflict of interest can be defined as any situation in which 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. Investigators, key research personnel, IRB members, and 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.

c. Research that Meets Criteria for Exemption. Experienced individuals such as IRB Chairs, IRB Vice Chairs, designated IRB administrators, or designated officials of the HRPP must determine and document whether research protocols meet one or more categories of exemption as defined in reference (b). Investigators may not make this determination and may not start any research activities until the exemption determination is made and documented.

d. Research that Meets Criteria for Expedited Review. Naval IRB Chairs or IRB Vice Chairs will review and determine whether research protocols meet criteria for review under expedited procedures as defined in reference (b).

e. Survey Research. Surveys, other than those executed entirely within the command, typically require Navy Survey Review and Approval per reference (h). The Navy Survey Approval Manager may require IRB review of the survey instrument prior to granting approval.

f. Collaborative Research. DON commands and activities may collaborate with each other, other DoD agencies, non-defense federal agencies, and non-federal institutions. An appropriate written agreement shall be established between the collaborators that includes a Statement of Work (SOW) and specific assignment of responsibilities. The agreement should briefly describe the research, specific roles and responsibilities of each institution, responsibility for scientific and IRB review, recruitment of subjects, and procedures for obtaining informed consent. The agreement also should describe provisions for oversight and ongoing monitoring, reporting requirements, documentation retention, and compliance for the entire research project. All collaborators must ensure compliance with all relevant human subject protection regulations at their sites. Collaborating institutions that rely on other institutions' IRBs for human subject protections to avoid duplication of effort must ensure that such reliance does not compromise any standards or requirements.

g. DON-Supported Extramural Research. DON supports research with human subjects conducted at non-federal institutions. Any research grants, contracts, cooperative agreements, Cooperative Research and Development Agreements (CRADAs), or other transactions must include the additional DoD and DON requirements for human subject protections.

h. Research Involving the Use of Investigational Test Articles. All research involving the use of investigational test articles (drugs, devices and biologics) shall comply with U.S. Food and Drug Administration (FDA) regulations, references (i) through (m). An Investigational New Drug (IND) application or an Investigational Device Exemption (IDE) must be filed with the FDA whenever research involving human subjects is conducted outside the United States with drugs, devices or biologics, which would require filing of an IND or an IDE if the research were conducted in the United States. Only the Navy SG,

Commanders, and Commanding Officers may be designated as sponsors for INDs and IDEs. The Navy SG may consider an IND/IDE equivalency in circumstances where the requirements may not be possible or feasible in international research. Investigators may not be designated as sponsors for INDs and IDEs.

i. 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 by this instruction will be followed. An ethics review by the host country, or local Naval IRB with host country representation, is required.

j. 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) (SECDEF Memorandum of December 13, 1999). Classified research is not eligible for review under expedited review procedures as noted in reference (n).

k. Allegations of Non-compliance with Human Subject Protections. The Naval command or activity with responsibility for the research will review all allegations of non-compliance with human subject protections and take action if appropriate. Report the initiation of all investigations and report results regardless of the findings to the Navy SG and appropriate sponsors.

l. Allegations of Research Misconduct. The Naval command or activity with responsibility for the research will review all allegations of research misconduct and take action if appropriate. Report the initiation of all investigations and report results regardless of the findings to the Navy SG and appropriate sponsors as outlined in references (o) and (p).

m. Public Release of Research Information. To foster public trust in research and human subject protections, information is made available to the public, the news media, and Congress. This information may be released after appropriate review and approval per references (q), (r), and other applicable guidance.

7. Authority and Delegation. In accordance with reference (a) the Secretary of the Navy delegates the authority and

responsibility for the DON Human Research Protection Program (HRPP) to the Navy SG, except for those specifically retained by the Secretary of the Navy and those delegated to the Under Secretary of the Navy.

a. Authority

(1) The Secretary of the Navy is the research approval authority for all research protocols involving:

(a) Waivers of the requirement for informed consent under reference (e).

(b) Exceptions from informed consent requirements for emergency research under 21 CFR 50.24 in reference (i) and in accordance with the requirements of reference (e).

(c) Requests for waiver of requirements of DON policy regarding human research protections.

(2) The Under Secretary of the Navy (UNSECNAV) is the Approval Authority for research involving:

(a) Severe or unusual intrusions, either physical or psychological, on human subjects (such as consciousness-altering drugs or mind-control techniques).

(b) Prisoners.

(c) Potentially or inherently controversial topics (such as those likely to attract significant media coverage or that might invite challenge by interest groups).

(3) The UNSECNAV forwards to the Director, Defense Research and Engineering (DDR&E) for final determination:

(a) All proposed research involving exposure of human subjects to the effects of nuclear, biological or chemical warfare agents or weapons, as required by reference (a).

(b) All human research protocols that would require action by an official of the Department of Health and Human Services under reference (f).

(4) UNSECNAV forwards to SECDEF, via DDR&E, for approval all classified human research.

(5) The Navy SG is the single authority for policy development, oversight, compliance, and ongoing monitoring concerning human research protections in the DON.

(6) The Navy SG holds the DON's assurance approval authority for new assurances, renewal of current assurances, and acceptance of other assurances. The Navy SG also holds the authority to restrict, suspend, or terminate DON assurances.

(7) The Navy SG is the Approval Authority for all research protocols, except:

(a) Those addressed in paragraph 7a(1) through 7a(4), which are forwarded by the Navy SG to higher authority via the Assistant Secretary of the Navy for Research Development and Acquisition (ASN(RDA)).

(b) Those for which the Navy SG delegates approval authority to Commanders, Commanding Officers, and Officers in Charge through an approved DoD Navy Assurance for the Protection of Human Research Subjects.

(8) Commanders, Commanding Officers, and Officers in Charge, who have been delegated the authority by the Navy SG to approve research protocols under their respective jurisdictions, may do so only after review and recommendation by:

(a) IRB Chairs and Vice Chairs for research that is eligible for expedited review, or

(b) An IRB after a convened meeting.

b. Delegation

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

(2) Commanders, Commanding Officers, and Officers in Charge may delegate to IRB Chairs and Vice Chairs 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.

(3) This authority may not be further delegated.

8. Responsibilities

a. The Surgeon General of the Navy

(1) Develops policies and programs for the DON HRPP.

(2) Establishes initial and ongoing research ethics and human subject protections education and training for all personnel involved in reviewing, approving, supporting, conducting, managing, or overseeing research involving human subjects.

(3) Verifies completion and documentation of research ethics and human subject protections training.

(4) Develops and maintains a DON HRPP Handbook to provide detailed, practical information to facilitate compliance with these requirements.

(5) Reviews and approves, if acceptable, requests for DoD Navy Assurances.

(6) Reviews and accepts, if appropriate, other DoD or federal assurances.

(7) Monitors institutions to ensure continued compliance with their assurances and such requirements as continuing review and reporting of unanticipated problems involving risks to subjects or others, or adverse events.

(8) Restricts, suspends, or terminates any assurance when institutions that hold DoD Navy Assurances fail to comply with DON requirements.

(9) Acts as the Approval Authority for research protocols, except for those research protocols:

(a) Forwarded to higher authority as stated in paragraphs 7a(1) through 7a(4).

(b) Approved by Commanders, Commanding Officers, and Officers in Charge who have been delegated this authority through an approved DoD Navy Assurance.

(10) Conducts headquarters-level administrative review of research protocols, including research that meets criteria for exemption, following local command or institutional review and approval. Based on the results of the review may request modifications or information, suspend, or terminate the research.

(11) Reviews and approves agreements between performing institutions prior to assigning IRB review, approval, and/or oversight to other institutions.

(12) Reviews and, if appropriate, takes action on all allegations of non-compliance with human subject protections.

(13) Reviews and, if appropriate, takes action on all allegations of research misconduct and reports all serious research misconduct to DDR&E per references (a), (o), and (p).

(14) Reports the following to DDR&E via ASN(RDA) and the UNSECNAV:

(a) All restrictions, suspensions, or terminations of DoD Navy Assurances or of other assurances awarded to DON institutions from other federal entities.

(b) All investigations of the DON HRPP conducted by outside entities (e.g., the FDA or the Office of Human Research Protections (OHRP)).

(c) All DON investigations of extramural performers that uncover violations.

(d) All findings of serious non-compliance with human subject protections per reference (a).

(e) Unanticipated problems involving risks to subjects or others, or serious adverse events, as appropriate.

(f) Significant communication between DON institutions conducting research and other federal departments and agencies regarding compliance and oversight.

(15) May serve as the sponsor for INDs and IDEs.

b. Chief of Naval Research: The Chief of Naval Research will provide support and expertise to the Navy SG for human research protections in the Systems Commands, operational

forces, training commands, and DON-supported extramural performing institutions.

c. Commanders, Commanding Officers, and Officers in Charge:

(1) Complete and document initial and continuing research ethics and human subject protections training.

(2) Ensure initial and ongoing research ethics education and training for all personnel involved in reviewing, approving, supporting, conducting, or managing research involving human subjects. In addition, education and training for investigational agent use for Force Health Protection is required by reference (c).

(3) Ensure that subjects' decisions to participate are voluntary and are protected from undue influence.

(4) Verify, for each research protocol, whether their institution is engaged in research as determined by their IRB(s). Require certification(s) (IRB approval) from the performing activity or activities before allowing the research to begin.

(5) Obtain a DoD Navy Assurance from the Navy SG and:

(a) Obtain a Federal wide Assurance (FWA) when the institution is engaged in Department of Health and Human Service (DHHS)-supported research.

(b) Verify that all collaborating institutions, domestic and international, hold a valid DoD, DON, or other federal assurance. (Note: Any institution may apply for these assurances.)

(c) Submit an updated assurance whenever the Institutional Signatory Official or IRB Chairs change.

(6) Ensure an independent review of research for scientific merit or scholarship prior to IRB review.

(7) Ensure IRB review of research by establishing IRBs and appointing IRB Chairs and Vice Chairs to review research, by relying on IRBs established under other assurances, or relying on independent IRBs.

(8) Serve as their institution's research approval authority contingent upon holding that delegated authority.

(9) May approve research protocols only after IRB review and recommendation for approval.

(10) May approve research protocols only after review and recommendation for approval by IRB Chairs or Vice Chairs for research that meets criteria for expedited review.

(11) May approve, require modifications to gain approval, disapprove new research protocols; require additional safe-guards, or refer the protocol to a higher approval authority, after reviewing and considering, at a minimum, the signed minutes of IRB meetings or the IRB Chair's written recommendations for research eligible for expedited review.

(12) May approve, require modifications to gain approval, or disapprove continuation of current research protocols; require additional safeguards, suspend or terminate the research based on specific criteria and the IRB's continuing review findings or the IRB Chair's written recommendations for research eligible for expedited review.

(13) Refer research protocols for which they are investiga-tors or members of the research team to a higher research approval authority for review.

(14) Adhere to or increase the safeguards or special conditions recommended by the IRB.

(15) Shall support IRB recommendations when research protocols are recommended for disapproval.

(16) Provide certifications of research protocol review and approval to funding organizations, sponsors, and collaborators.

(17) Submit all research protocols and supporting docu-mentation for Navy SG headquarters-level administrative review.

(18) Maintain appropriate research records in a retrievable format as "Project Case Files" as required by reference (s).

(19) Allocate resources adequate to ensure compliance with the institution's assurance and all applicable guidance.

(20) Negotiate appropriate written agreements with participating institution(s) for cooperative/collaborative research projects per paragraph 6f of this document. Obtain approval from the Navy SG for agreements relying on IRBs established under other assurances or relying on independent IRBs.

(a) Institutions using a standard agreement may negotiate and submit the finalized agreement with the applicable research protocol to the Navy SG for headquarters-level administrative review.

(b) Institutions electing to use agreements other

than a standard must submit their proposed alternative to the Navy SG prior to finalizing the agreement.

(21) Review and, if appropriate, take action on any allegations of non-compliance with human subject protections.

(22) Review and, if appropriate, take action on any allegations of research misconduct.

(23) Report the following to the Director, DON HRPP and appropriate sponsor(s):

(a) Unanticipated problems involving risks to subjects or others, or serious adverse events.

(b) All suspensions or terminations of previously approved research protocols.

(c) The initiation of all investigations of non-compliance with human subject protections.

(d) The results of all investigations of non-compliance with human subject protections, regardless of the findings.

(e) The initiation of all investigations of research misconduct.

(f) The results of all investigations of research misconduct, regardless of the findings.

(g) All audits, investigations, or inspections of a DON-supported research protocol.

(h) All audits, investigations, or inspections of the institution's HRPP conducted by an outside entity (e.g., the FDA or the Office of Human Research Protections (OHRP)).

(i) Significant communication between the institutions conducting research and other federal departments and agencies regarding compliance and oversight.

(24) Only Commanders, Commanding Officers, or the Navy SG may serve as sponsors for INDs and IDEs.

d. DON-Supported Extramural Performers and Performance Sites. The responsibility for appropriate protection of human subjects in research lies with the performing institution. The institutions must:

(1) Submit the following to the DON HRPP Office prior to award:

(a) An appropriate institutional assurance (e.g., a FWA or DoD assurance) or an application for a DoD Navy Assurance.

(b) Written acknowledgement that the institution will comply with references (a), (b), and when applicable, (i) through (m).

(c) Documentation of the IRB's initial and continuing review and approval.

(d) IRB-approved informed consent form, except when not required consistent with law and regulation.

(e) IRB-approved research protocol.

(f) Documentation of completed research ethics and human subject protections training by the principal investigator.

(2) Report the following to the DON HRPP Office and appropriate sponsor(s):

(a) All suspensions or terminations of previously approved DON-supported research protocols.

(b) The initiation and results of investigations of alleged non-compliance with human subject protections.

(c) Unanticipated problems involving risks to subjects or others, or serious adverse events in DON-supported research.

(d) All audits, investigations, or inspections of DON-supported research protocols.

(e) All audits, investigations, or inspections of the institution's HRPP conducted by outside entities (e.g., the FDA or OHRP).

(f) Significant communication between institutions conducting research and other federal departments and agencies regarding compliance and oversight.

(g) All restrictions, suspensions, or terminations of institutions' assurances.

e. Naval IRBs. The primary role of the IRB is to ensure the safety and welfare of human research subjects. IRBs make recommendations to the approval authority for research protocols. Naval IRBs:

(1) Must be composed of members who are current federal employees, individuals appointed under the Intergovernmental Personnel Act (IPA), or consultants consistent with the requirements established by reference (t). Status as a contractor or federal retiree alone is not sufficient to qualify as a federal employee for the purpose of IRB membership.

(2) Complete and document initial and continuing research ethics and human subject protections training.

(3) Determine, for each research protocol, whether their institution is engaged in research. Require certification(s) (IRB approval) from the performing activity or activities.

(4) Review and, if appropriate, take action on any allegations of non-compliance with human subject protections.

(5) Consult with other committees as appropriate (i.e., radiation safety, biosafety).

(6) Report to the Commander, Commanding Officer or Officer in Charge:

(a) All suspensions or terminations of previously approved research protocols.

(b) The initiation of investigations of alleged non-compliance with human subject protections.

(c) Unanticipated problems involving risks to subjects or others, or serious adverse events.

(d) All audits, investigations, or inspections of the institution's HRPP conducted by an outside entity (e.g., the FDA or the Office of Human Research Protections (OHRP)).

(e) Significant communication between the institutions conducting research and other federal departments and agencies regarding compliance and oversight.

f. Chairs and Vice Chairs of Naval IRBs. IRB Chairs and Vice Chairs, if delegated authority from the research approval authority, may review and make recommendations for research that meets criteria for expedited review procedures. IRB Chairs and Vice Chairs:

(1) Complete and document initial and continuing research ethics and human subject protections training.

(2) May suspend research due to unanticipated problems involving risks to subjects or others, or serious adverse events involving subjects or others, significant deviation from approved protocols, or for reasonable cause.

g. Principal Investigators (PIs). PIs have primary responsibility for compliance with all human subject protection regulations, directives, and instructions. Principal Investigators in DON-supported intramural research:

(1) Must be current federal employees. Status as a contractor or federal retiree alone is not sufficient to qualify individuals as principal investigators for such research.

(2) Complete and document initial and continuing research ethics and human subject protections training.

(3) Obtain written determination of whether the proposed activity is research with human subjects or the research meets criteria for exemption per reference (b).

(4) Obtain institutional approval prior to conducting or continuing research.

(5) Obtain institutional approval prior to implementing proposed amendments to approved research.

(6) Notify the IRB in writing of unanticipated problems involving risks to subjects or others; serious adverse events; serious or continuing noncompliance with the human subject protection regulations and IRB requirements; and protocol deviations.

(7) Obtain informed consent from research subjects or their legally authorized representatives and provide them a copy of the completed informed consent document prior to the start of research, unless a waiver of the documentation is approved by the institution.

h. Clarification Contact. Any specific situations not addressed in this instruction should be referred to the Navy SG for clarification.

i. Reports. Reporting requirements contained in paragraphs 6k, 6l, 8a(14), 8c(23), 8e(6), and 8g(6) are exempt from reports control of reference (u).

Donald C. Winter
Secretary of the Navy

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DEFINITIONS RELATED TO DON HRPP

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

2. 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.

3. Assurance. See Institutional Assurance.

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

5. 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. [32 CFR 219.102(j)]

6. 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 obtain individually identifiable private information for research purposes. [Office for Human Research Protections (formerly OPRR) memo of January 26, 1999]

7. 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.

8. Headquarters-Level Administrative Review. Administrative review of approved research protocols by a designated Naval Research Approval Authority to verify regulatory compliance and human research protections following local approval.

9. Human Subject

a. Means a living individual about whom an investigator (whether professional or student) 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 (for example, 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. 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 (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. [32 CFR 219.102(f)]

b. Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. [21 CFR 50.3(g) and 21 CFR 56.102(e)]

10. Institution. For the purposes of this instruction, institution refers to Navy and Marine Corps commands, units, activities, and detachments.

11. Institutional Assurance. A document originated by an institution engaged in research supported by the DOD stating that it will comply with federal regulations, DOD, and DON requirements for human subject protections.

12. Institutional Review Board (IRB). The IRB is a committee established in accordance with 32 CFR 219 to review research to ensure the protection of the rights and welfare of human research subjects.

13. Institutional Review Board (IRB) 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 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.

14. Institutional Signatory Official. A senior institutional official (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 Institutional Signatory Official.

15. Investigational Test Article. 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."

16. 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. [32 CFR 219.102(i)]

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

18. Non-compliance. Deliberate or inadvertent departure from or failure to comply with federal regulations, DOD directives, DON instructions, or IRB requirements for the protection of human research subjects.

19. Principal Investigator (PI). In DON-supported human subject research, an individual 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. In addition:

a. For DON-supported Intramural Research. A Principal Investigator must be a current federal employee (uniformed or civilian, staff, or trainee), covered under the Intergovernmental Personnel Act (IPA), or a consultant consistent with the requirements established by 5 USC 3109, and must be assigned to or employed by a specific command. Status as a contractor or federal retiree alone is not sufficient to qualify individuals as principal investigators for such research.

b. For DON-supported Extramural Research. A Principal Investigator must meet the criteria established by the institution that receives the award.

20. 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. [45 CFR 46.303(c)]

21. Prisoner of War (POW). A detained person as defined in Articles 4 and 5 of the Geneva Convention Relative to the Treatment of Prisoners of War of August 12, 1949. In particular, one who, while engaged in combat under orders of his government, is captured by the armed forces of the enemy.

22. Protocol. The detailed written research plan.

23. Research. Any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. [32 CFR 219.102(d)]

a. 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.

b. 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 21 CFR 56.101(c) and 21 CFR 50.3(c)]

24. Research Misconduct. Means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

a. Fabrication is making up data or results and recording or reporting them.

b. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

c. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

d. Research misconduct does not include honest error or differences of opinion. [42 CFR 93.103]

25. Risk. Any possibility of harm, discomfort, or injury (physical, psychological, sociological, or other) as a consequence of any act or omission. (See Minimal Risk.)

26. 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. [21 CFR 56.102(l) and 21 CFR 50.3(j)]