



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
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IN REPLY REFER TO

3900
Ser 04UM00RIE1/0252
15 Jul 04

From: Chief, Bureau of Medicine and Surgery

Subj: INTERIM GUIDANCE FOR INTEGRATING REQUIREMENTS FOR THE ETHICAL PROTECTION OF HUMAN RESEARCH SUBJECTS

Ref: (a) BUMEDINST 3900.6B, Protection of Human Subjects
(b) BUMEDINST 6000.12A, Clinical Investigation Program (CIP)
(c) NSHSBETHINST 6000.41B, Clinical Investigation Program (CIP)
(d) SECNAVINST 3900.39C, Protection of Human Subjects
(e) 21 Code of Federal Regulations 50
(f) through (bb), see enclosure (1)

Encl: (1) References (f) through (bb)

1. Purpose. To provide interim clarification and guidance for the ongoing implementation of references (a), (b) and (c) in light of new and emerging federal and Department of Defense (DoD) requirements. The provisions below integrate requirements found in references (a), (b) and (c).

2. Scope. The requirements of references (a), (b) and (c) and the provisions in this document are requirements for all Navy and Marine Corps activities and related personnel conducting, supporting, or participating in human research efforts as placed under the authority of the Surgeon General of the Navy per paragraph 7b of reference (d). "Research" and "clinical investigation" are defined in references (e) and (f). Research and clinical investigations include, but are not limited to, those activities traditionally known as medical and non-medical research and development, tests and evaluation, clinical investigation, socio-behavioral investigation, human performance efforts, student research, and any other research or investigation regardless of academic discipline.

3. Action. The provisions of this document are effective immediately and remain in effect until revised comprehensive policy for the ethical protection of human research participants is distributed. This guidance supersedes previous guidance on these specific topics. Higher authority will review, monitor and audit compliance with the provisions of this document; therefore, address new items as soon as possible.

4. Background.

a. References (g) and (h) created the Special Assistant to the Surgeon General for Research Integrity and Ethics (M00RIE), as well as the Office of Research Integrity and Ethics (ORIE) under the Director for Research and Development (M2), Bureau of Medicine and

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Surgery (BUMED) as related dual entities. One of the objectives in this initiative was to create a single, unified Human Research Protections Program (HRPP) for all efforts assigned by higher authority under the authority and responsibility of the Surgeon General of the Navy.

b. Within this matrix organization, the Clinical Investigation Program was realigned under ORIE-HRPP. Reference (i) detailed specific changes for HRPP policies and procedures for Research and Development activities while reference (j) detailed specific changes for HRPP policies and procedures for Clinical Investigation Program activities.

c. The new organizational alignment and emerging requirements from higher authority necessitate the formulation and issuance of a new, single, comprehensive policy for the protection of human research subjects that addresses all Navy and Marine Corps circumstances and programs. Such revision requires the detailed input of subject area experts from all relevant Navy and Marine Corps sectors. The plan for a new policy-working group will be announced shortly.

d. Until the plan for the working group is complete and new policy is issued after appropriate community input and comment, interim measures are needed to integrate the requirements of present policies in references (a), (b) and (c) with new and emerging norms and directions from various federal, DoD and international levels. This document begins the goal of integration.

5. Specific Provisions.

a. Naval Medicine Assurances (NMA).

(1) The Naval Medicine Director for Human Research (DHR) is the Assurance Issuing Official for Naval Medicine under authority delegated by references (d) and (k). The DHR discharges Assurance Issuing Official responsibilities in the dual role as Director, ORIE-HRPP.

(2) Any Naval or Marine Corps activity conducting, supporting, or participating in human research efforts, regardless of sponsor or subject area, must hold a current Naval Medicine assurance as granted by the DHR. Qualifying research-related efforts are all those that fall under federal definitions for human subjects research. However, higher authority or local activities may include other efforts not specifically defined by federal regulations as human subjects research per paragraph 101 of reference (f). References (i), (j) and (l) confirmed and assigned NMA numbers and implemented Institutional Review Board (IRB) registration.

(3) In addition to the NMA, any Navy or Marine Corps activities conducting, supporting or participating in research supported by other federal agencies must have an assurance from that agency, confirm that the agency will accept the NMA, or confirm that the agency will accept another federal agency's assurance. The Federal wide Assurance (FWA) awarded by the Office of Human Research Protections (OHRP) at the Department of Health and Human Services (DHHS) is accepted by the Department of

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Defense activities and other federal agencies. However, at this time DHHS does not accept or recognize DOD assurances. Therefore, Navy and Marine Corps activities engaged with DHHS sponsored research must hold both the NMA and FWA. ORIE-HRPP will advise local activities regarding FWA necessity/applicability and the FWA application process. When applying for a new FWA or renewal of an FWA, the application, including appropriate and applicable IRB registrations, must be forwarded to ORIE-HRPP prior to submission to OHRP. ORIE-HRPP will provide endorsement of the application and cross-agency clarifications with OHRP.

(4) When Naval activities collaborate with other commands, agencies, institutions or universities, they must verify that the collaborators have the appropriate assurances and certifications described in references (b), (c), (d), and (f). As appropriate, Naval activities may make arrangements to rely on another qualified IRB to avoid duplication of effort without compromising human subject protections. Other dimensions of collaboration may be arranged with appropriate agreements.

b. Education and Training. Reference (k) requires research ethics training as well as training in all standards for the responsible conduct of research (RCR) in all activities that review, approve, conduct, or participate in human subject research. All activities must provide and document training for all personnel that is commensurate with their duties and responsibilities in the protection of human research subjects. The training must be substantive, continuous, contain measures of accountability and be documented. HRPP will set educational standards, and will provide information and access to resources that meet these requirements. Activities may use alternatives provided that they meet the standards to be set by HRPP. Personnel may not participate in human subject research unless they meet initial and continuing education requirements.

c. Scientific Review. Historical perspectives and emerging national standards both support the critical need for scientific review of research prior to and separate from ethical review. All research involving human subjects, including new protocols and amendments to previously approved and active protocols, must have an independent scientific review and approval by the local institution or collaborating institution prior to review by the IRB. Appropriate individuals, committees and/or groups other than the IRB must complete scientific review. While activities may choose from a wide variety of resources for such review, it is not permissible for scientific review to be accomplished by the IRB *per se* since the focus of the IRB, whose membership includes non-scientists, is upon ethical protections for subjects and not review for scientific merit or scholarship. The PI must submit documentation of scientific review and approval of the research protocol for the IRB to consider in their review.

d. Headquarters Level Administrative Review (Second Level Review). Second level review has its origins in reference (k) where it is referred to as headquarters level administrative review of research. Reference (k), however, does not define this review and leaves implementation to each component and/or assurance-issuing office. Navy implementation is first cited in reference (d). To provide for second level review of research as required by reference (d), HRPP has established and will oversee a system of review strategies. For all relevant Navy and Marine Corps activities, second level review is defined as post-approval, quality assurance

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monitoring. It does not constitute a second IRB review or a second approval from higher authority. Consistent with this policy, certification of second level review must be a “concurrence” and not an “approval”. However, HRPP officials can require additional action or materials based upon second level reviews. In addition, HRPP officials have the obligation to intervene and suspend research efforts in the case of noncompliance and/or potential misconduct. Second level reviews are required for all new protocols, continuing reviews, amendments, deviations, unanticipated problems and adverse events, and final reports. To complete second level reviews and maintain the highest standards of ethical protections, all research protocol submissions must be received at the designated second level review office no later than ten working days after final approval from the institutional official (for submissions reviewed by the convened IRB) or by the IRB Chair (for submissions reviewed under expedited review procedures or for protocols meeting exempt criteria). For Research and Development Echelon 3 commands, guidance for second level review of human subjects research at subordinate commands was given in reference (m) and remains in force.

e. Definition of Investigator. Individuals who are federal employees (uniformed or civilian), individuals covered under the Intergovernmental Personnel Act (IPA), or consultants consistent with the requirements established by reference (n) may serve as Principal Investigators for human subjects research. Individuals must possess the required education, knowledge, skills, experience and expertise to serve in that position. The IRB ultimately has the responsibility to assess and verify the PI’s qualifications.

f. Conflict of Interest. Conflicting and competing interests can occur with individuals involved with the review, support, conduct and oversight of research with human subjects. References (a), (f), and (o) note that IRB members with a conflicting interests may not participate in the IRB’s initial or continuing review of that research. If the IRB Chair or the Command’s approval authority is involved in a research protocol, or if other conflicting or competing interests exist, these individuals may not review or approve the research and the reasons for the recusal should be documented. The next higher echelon in the chain of command must review the research protocol. Investigators must also disclose any financial interests or support for the research so that the command may devise a plan to manage the conflicts and IRB may determine whether this information should be shared with potential research subjects. In addition, IRB members, IRB staff and institutional officials may have conflicting or competing interests that must be disclosed and addressed. Those individuals the IRB confirms as medical monitors shall be independent of the research team itself. Unless there are extenuating circumstances, the medical monitor shall not be from the same primary department conducting the research.

g. IRB Composition and Authority.

(1) The overall mission of the IRB is to assure the protection of the rights and welfare of human participants from research risks. Ethical assessment and decision-making are central to the IRB mission.

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(2) An IRB must have a minimum of five members, including at least one member whose concerns are in non-scientific areas and at least one member who is not affiliated with the institution as indicated in reference (f).

(3) A quorum is required for the valid conduct of IRB business. A quorum is defined as the simple majority (one more than half) of the regular voting membership including the presence of a non-scientist. Without a quorum, an IRB can not hold a valid meeting.

(4) As a matter of practice and to avoid conflicts of interest, staff members who provide direct expert or administrative support to the IRB may not be voting members. Those individuals may serve as *ex officio*, non-voting members.

(5) The IRB chair should be a non-voting regular member who would vote only in the case of a tie.

(6) Reference (d) stipulates that the institutional official or commanding officer is the final approval authority and that the IRB makes recommendations to the approval authority. As such, IRB documentation should indicate that IRB actions are recommended for approval (e.g. IRB meeting minutes, correspondence to investigators etc., should use the terms “recommend approval”, “recommend modifications that may be reviewed under expedited review procedures”, “recommend tabling the review for the convened IRB to review the PI’s response to the IRB’s concerns”, or “recommend disapproval”). The IRB should not use the term “approval pending” or “approval”.

(7) References (f) and (p) note that the IRB may suspend or terminate an approved research protocol that is not being conducted in accordance with the IRB’s requirements or research that has been associated with unexpected serious harms to subjects. The IRB may also suspend or terminate research when there is indication of serious or continuing non-compliance and where there are unanticipated problems involving risks to subjects or others.

(8) For multi-site efforts among activities holding an NMA, activities may make arrangements to name an IRB of record and thus avoid unnecessary duplication of IRB review while ensuring that the local institutional official still provides approval. For multi-site efforts with extramural collaborators or partners, duplication of effort should be avoided, provided that requirements for assurance acceptance and determination of IRB of record are met. In all cases, DoD/Navy requirements must be met and cannot be waived.

h. Exempt Research and Determination of Qualification as Human Subjects Research. “Human Use Policy #3, Exempt Research, dated 22 February 2002 (Supplemental Policy to BUMEDINST 3900.6B)” is superseded by the guidance in reference (f) paragraph 101b. Federal regulations state that certain categories of research whose risk is considered negligible may meet criteria for exemption from the regulatory requirements. The investigator cannot make the determination that research meets criteria for exemption. Determination of exempt status,

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identical to the determination of whether an effort does or does not qualify as human research, can only be made by either: the IRB Chair, the entire IRB, or qualified members of IRB policy offices, Clinical Investigation Departments, or the relevant Offices of Research Administration, as applicable. Determination by investigator or research staff of exempt status or determination of qualification as human subject research constitutes a conflict of interest.

i. Research Eligible for Review Under Expedited Review Procedures. “Human Use Policy #4, Expedited Review and Approval Procedure, dated 14 February 2002 (Supplemental Policy to BUMEDINST 3900.6B)” is superseded by guidance in reference (f) paragraph 110 and reference (q). A summary of reference (q) may be found on the OHRP website at the following link: <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>.

j. Continuing Review. “Human Use Policy #5.1, Continuing Review, dated 22 April 2003 (Supplemental Policy to BUMEDINST 3900.6B)” is superseded by the following guidance. Continuing reviews for all research protocols determined to be greater than minimal risk must be conducted at an interval more frequently than once every 365 days (1 year) consistent with standards emerging from the Office for Human Research Protections (OHRP) and the U.S. Food and Drug Administration (FDA). The Institutional Review Board (IRB) will determine the interval of the continuing review based on the criteria outlined in reference (f) paragraphs 109.e and 111, and as appropriate to the research protocol’s inherent risks/harms and potential benefits. IRB determination of continuing review frequency is a matter for on going monitoring by ORIE-HRPP. Local commands should establish procedures for conducting continuing review.

k. Unanticipated Problems including Serious Adverse Events. “Revised Human Use Policy #2.1, Adverse and Serious Adverse Events, dated 21 February 2002 (Supplemental Policy to BUMEDINST 3900.6B)” is superseded by the following guidance. For reporting unanticipated problems and serious adverse events (SAE), follow the guidance in references (d), (p), (r), (s), (t) and the following:

(1) All research protocols must contain a plan for monitoring the data collected to ensure the safety of subjects including reporting of adverse events as indicated in reference (f) and actions that will be taken in the event of unanticipated problems and/or adverse events. The plan must also address the additional requirements for a medical monitor in research involving more than minimal risk as required by references (a), (c), (d) and (k).

(2) PIs must report, by electronic, telephone or other means, both expected, serious adverse events and unanticipated, serious adverse events to the IRB Chair within 24 hours of discovery. PIs must also notify the medical monitor as expeditiously as possible for an assessment. In addition, PIs must notify affected subjects as soon as feasible.

(3) The IRB Chair and local approval authority, in timely consultation with one another, must determine whether it is necessary for the event to be reported immediately in writing to the Director for Human Research (DHR), BUMED.

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(4) PIs must promptly submit detailed written reports concerning the event to the IRB for review as appropriate. After IRB review, a copy of the event report and the action of the local approving official must be sent to the DHR in a timely manner.

(5) In addition, investigators and local activities must comply with all requirements of research sponsors and the FDA for the prompt and complete reporting of all research deviations, unanticipated problems, and adverse events.

(6) Reference (d) requires that investigators report a summary of adverse events with each continuing review. Local activities must provide clear guidance to investigators for reporting detailed summaries of unanticipated problems, adverse events and protocol deviations as part of the continuing review requirement.

l. Issues of Public Affairs Interest. If any complicating event of any magnitude occurs in a human research study that would be of Public Affairs importance or interest to the DoD/Department of the Navy (DON) or the Office of the Surgeon General of the Navy, the local approving official or Commanding Officer must notify the DHR within 24 hours of discovery. The DHR will in turn notify the BUMED Office of Public Affairs. The DHR will determine the requirement for a written report that may include further action from public affairs.

m. Investigational New Drugs (IND) / Investigational Device Exemptions (IDE). The use of investigational drugs, biologics and devices in studies involving human subjects must comply with the instructions and directives in references (d), (r), (s), (t), (u) and (v). An IND or IDE must be filed with the FDA whenever research involving human subjects is conducted outside the United States with drugs, biologics or devices, which would require filing of an IND or IDE if the research were conducted in the United States. In special circumstances where this may not be possible or feasible in research conducted overseas, an IND/IDE equivalency may be considered by the DHR following review by an ad hoc expert panel.

n. Compliance with the Privacy Rule and Health Insurance Portability and Accountability Act (HIPAA) of 1996. HIPAA requirements specified under reference (w) are applicable to those institutions that qualify as covered entities. For those institutions that qualify as business associates, requirements of collaborating institutions that are covered entities must be met. All research protocols, informed consent documents, and other related matters must meet Privacy Act and HIPAA requirements as specified under references (w) and (x).

o. Socio-Behavioral and Humanities Research. The possibility and gravity of unanticipated problems or harms to subjects or others are not confined to biomedical, medical, or health related studies. Socio-behavioral and humanities research carry with them the same potential. Medical studies themselves carry the potential for non-medical complications and factors that must be addressed with equal weight. Local activities must adopt provisions to increase awareness of and sensitivity to complicating events that require IRB review, assessment, and amelioration. Local manuals and instructions must include detail and operational direction for how such matters are to be addressed and resolved by the IRB and approval authorities.

p. Surveys. For those human research protocols in which the sole purpose is to gather information from subjects through the administration of a survey, the requirements of reference

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(y) must be met. Paragraph 9 of reference (y) lists the requirement that must be met for approval from the requisite higher authority. The review and approval of the survey must be documented and submitted with the research protocol for the IRB to consider in their review. If higher authority requires IRB assessment of the survey instrument prior to the granting of survey approval, local activities are to adjust procedures accordingly.

q. State Laws. All research must conform with all local and State regulations, in addition to those of the U.S. federal government, DoD and DoN. In the case of conflicting standards, stricter interpretations must always apply.

r. International Research. Research protocols that are conducted outside the jurisdiction of the United States require careful consideration to ensure the rights and welfare of human research subjects. Investigators and IRBs must carefully address the cultural, sociological structure, and other human factors that are unique to the population involved in the research. The IRB must also consider the laws, customs and practices of the host country. In conjunction with the research activity, it is an ethical imperative to consider the highest possible commitment to capacity building in the local context. Paragraph 6.e of reference (d) directs that all research conducted outside the United States shall meet the same standards of ethics and safety that apply to research within the United States. However, it is to be noted that when standards conflict, the stricter standard and/or interpretation must take precedence.

(1) Where relevant, all activities must institute, in standard operating procedures and manuals, clear directions and methods for international research efforts. Such efforts must take into account ethical matters of international importance and of importance to the population involved.

(2) Local ethical approval for the research itself and the involvement of the population is required. This local ethical approval requirement may be met by a variety of means including, but not limited to, host country approval, Ministry of Health approval, and voting membership of representative populations as members on Naval IRBs.

(3) Naval IRBs must include appropriate members of the population involved in the research as voting members. Foreign Service Nationals (FSN) may serve as IRB members. Due to the sensitivity of meeting international ethical considerations, IRBs must include the presence of at least one of the international voting members as part of the quorum. This additional requirement would not be applicable if an international-based or sponsored research protocol were to enroll only United States citizens or members of the United States Armed Forces and their dependents living in the host country.

(4) In addition to local ethical approval, activities conducting international research must ensure that there is requisite permission from the host country. Such permissions are dependent upon the host country and may include arrangements for review of specific research protocols or permissions may be included under Status of Forces Agreements. Such permission is often inherent when local Ministries of Health provide ethical review and approval.

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(5) Due to the inherent nature of the dual review processes, the IRB and approval authorities may begin to consider a research protocol prior to the finalization of these reviews. However, research protocol approval cannot be granted nor human research subjects enrolled before required ethics and/or host country approvals, as applicable, are obtained.

(6) The IRB Chair and the local approval authority are responsible for ensuring that all local ethical and any required governmental approvals are granted in accordance with host country law and practice. However, standards of conduct for international studies must conform to all federal and DoD/DON regulations. In the case of conflicting standards, stricter interpretations must always apply.

s. Waivers of the Informed Consent Process. The informed consent process mandated by 10 USC 980 may only be waived in accordance with the policies in reference (v) and (z). At the present time, waivers from the requirements of 10 USC 980 may only be granted at the Secretarial level. In addition, only the President of the United States may grant a waiver of informed consent to use an investigational new drug for force health protection in connection with members' participation in particular military operations, and only the Secretary of Defense may request that the President grant such a waiver. Local activities must exercise extreme care in adhering to these requirements. In addition, local activities must inform extramural collaborators that these requirements are enjoined on all DoD sponsored human research, both intramural and extramural.

t. Addressing Research Non-Compliance and Misconduct. Each activity must have a local policy and procedure for addressing complaints, allegations of non-compliance or allegations of research misconduct as found in reference (k), (aa) and (bb). Any allegations brought to the institution, the IRB, the Clinical Investigation Department (CID) or an Office of Research Administration (ORA), must undergo an initial inquiry to determine whether the allegations are related to non-compliance with human research protections and/or meet the criteria for scientific misconduct. A local level independent committee, with input from the IRB, will investigate allegations of non-compliance with human research protections. The local command will take action as appropriate and forward the results to the DHR and ORIE-HRPP for further review and possible action. Similarly, an appropriate local level independent committee, with input from the IRB, will further investigate allegations of potential scientific misconduct. The local command will take action as appropriate and forward the results to the DHR and ORIE-HRPP for further review and possible action. All findings of serious non-compliance and/or serious research misconduct will be reported to DDR&E.

u. Resources for Local Human Research Protections Programs. As required by references (c) and (d), effective local programs require appropriate resources, including financial, logistics, support of scientific review, ethical review and education/training of science review and ethics review board members and administrative staff. Each activity must ensure that local Human Research Protections Programs are resourced sufficiently to meet and exceed all ethical, regulatory, and legal requirements for the protection of the rights and welfare of human research participants.

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6. My point of contact for any questions is CDR Eileen Villasante at (301) 530-5734,
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REFERENCES, continued

- (f) 32 Code of Federal Regulations 219
- (g) BUMEDINST 5430.6A CH-2, Bureau of Medicine and Surgery Organization Manual
- (h) Chief, BUMED letter 3900 Ser 04UM00RIE/0102 of 20 Feb 04
- (i) Chief, BUMED letter 3900 Ser M2/03U0149 of 12 Sep 03
- (j) Chief, BUMED letter 5000 Ser 04UM00RIE/0109 of 28 Apr 04
- (k) DoD Directive 3216.2, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, of 25 March 2002
- (l) Chief, BUMED letter 3900 Ser M00IE/030164 of 24 Sep 03
- (m) Chief, BUMED letter 3900 Ser M00RIE/3450004 of 11 Dec 03
- (n) 5 United States Code 3109
- (o) 69 Federal Register 26393 – 26397 of 12 May 04
- (p) 21 Code of Federal Regulations 56
- (q) 63 Federal Register 60364 - 60367 of 9 Nov 98
- (r) 21 Code of Federal Regulations 312
- (s) 21 Code of Federal Regulations 812
- (t) 21 Code of Federal Regulations 600
- (u) BUMEDINST 6710.69, Use of Investigational Agents in Humans
- (v) DoD Directive 6200.2, Use of Investigational New Drugs for Force Health Protection, of 1 Aug 00
- (w) 45 Code of Federal Regulations 160 and 164
- (x) SECNAVINST 5211.5D, Department of the Navy Privacy Act (PA) Program
- (y) OPNAVINST 5300.8B, Coordination and Control of Personnel Surveys
- (z) 10 United States Code 980
- (aa) 65 Federal Register 76260 - 76264 of 6 Dec 00
- (bb) DoD Directive 3210.7, Research Integrity and Misconduct, of 14 May 04