



DEPARTMENT OF THE NAVY
NAVAL MEDICAL RESEARCH CENTER
503 ROBERT GRANT AVENUE
SILVER SPRING, MARYLAND 20910-7500

IN REPLY REFER TO:

NAVMEDRSCHCENINST 3900.4

OOR

AUG 16 2002

NAVMEDRSCHCENTER INSTRUCTION 3900.4

From: Commanding Officer, Naval Medical Research Center

Subj: ESTABLISHMENT OF SCIENTIFIC REVIEW BOARD FOR HUMAN RESEARCH
PROTOCOLS

- Ref:
- (a) 32 CFR 219 "Protection of Human Subjects"
 - (b) DoD Directive 5000.1 of 23 October 2000 "The Defense Acquisition System"
 - (c) DoD Directive 3216.2 of 25 March 2002 "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research"
 - (d) SECNAVINST 3900.39C of 25 February 2002 "Protection of Human Subjects"
 - (e) BUMEDINST 3900.6B "Protection of Human Subjects"
 - (f) NAVMEDRSCHCENINST 3900.6A "The Protection of Human Subjects in Research"
 - (g) DoD Directive Interpretation, Office of the Assistant Vice President for Research, Uniformed Services University of the Health Sciences. Email of 23 May 2002.
 - (h) Standards and Requirements for the Responsible Conduct of Research, Office of Research Integrity, Department of Health and Human Services.

1. Purpose. To establish the Naval Medical Research Center (NMRC) Scientific Review Board (SRB) for the scientific review of human research proposals for the Naval Medical Research Center (NMRC) and the Naval Medical Research Center Detachment (NMRCD) in accordance with the requirements found in references (a) through (f). These requirements are underscored in reference (h) as clarified and/or interpreted by references (c) and (g).

2. Scope. All NMRC and NMRCD-related investigators, directorates and departments must fulfill SRB review and approval requirements prior to submitting human research proposals to the NMRC Institutional Review Board (IRB). Echelon 4 activities are to ensure that scientific review of all human research protocols is accomplished prior to submission to respective Institutional Review Boards (IRB). In the event of circumstances, Echelon 4 Commanding Officers may request the services of the NMRC SRB to accomplish these same purposes. Unless specifically directed below, Echelon 4

~~AUG 16 2002~~

Commands are to adapt the principles of this instruction on the local level.

3. Responsibility. The Office of Research Administration (ORA) is directed with responsibility for NMRC SRB executive administration including the establishment of SRB policies, standard operating procedures and services. The ORA Director will appoint ORA senior and subordinate personnel to serve SRB management and assistance needs as appropriate (e.g. Executive Administrator, Administrative Assistant etc).

4. SRB Membership.

a. The SRB will be composed of all NMRC and NMRC D personnel who would qualify as principal or associate investigators on research projects by virtue of academic credentials, subject matter expertise, and/or research experience. Determination of personnel qualification is the responsibility of scientific directors for their respective personnel. Within NMRC/NMRC D, SRB membership includes all military, GS, IPA, grants and contractor personnel.

b. The Commanding Officer will appoint a senior NMRC scientist to serve as the permanent SRB Chair. The Commanding Officer also may appoint an additional senior NMRC scientist to serve as Vice-Chair or Deputy.

c. With the permission of their institutions or supervisors and provided that there is no conflict of interest either generally or for particular protocols, extramural subject matter experts may serve as NMRC SRB members. The SRB Chair will be responsible for the appointment of extramural subject matter experts to the NMRC SRB.

d. ORA will make available to all SRB members continuing education materials regarding relevant policies especially those pertaining to standards for the responsible conduct of research.

5. Procedures and Related Matters.

a. NMRC-SRB scientific review and approval are required of all human use protocols and related materials prior to submission to ORA for IRB consideration. No materials can be considered by the IRB prior to the completion of scientific review and approval requirements set by the NMRC-SRB.

AUG 16 2002

b. Per reference (f), all investigators are required to forward all human research proposals and related materials through their regular chain of command to Directors/NMRCD-OIC for SRB consideration. Upon receipt of a new human use proposal, or other related materials, the respective Director/NMRCD-OIC will submit the material with standard cover correspondence to ORA requesting SRB review and approval.

c. Upon notification by ORA of receipt of materials requiring SRB review and approval, the SRB Chair will contact pertinent Directors and/or the NMRCD-OIC to determine which members of the general SRB membership would be most appropriate for scientific review and approval of the materials received. From those suggested as most appropriate, the SRB Chair will appoint and convene a Scientific Review Panel (SRP) within three (3) business days of receipt of the materials to ORA. ORA staff immediately will provide the review materials to the SRP by whatever means possible.

d. Each SRP will be composed of not less than three (3) but not more than five (5) members of the SRB with one designated as Coordinator. To ensure freedom from any perception of conflict of interest, none of the SRP members can be from the department(s) of the submitting scientist(s). One must be from outside the submitting scientist's Directorate. The SRB Chair will ensure that each SRP obtain statistical analysis as applicable and needed.

e. Each SRP will be required to complete its review within ten (10) working days from the time the SRP has been named and convened by the SRB Chair. Results will be reported directly by the SRP Coordinator in intramural correspondence to the SRB Chair. The SRB Chair will immediately submit results to the originally submitting Director/NMRCD-OIC. It will be the responsibility of each Director/NMRCD-OIC to address any needs or scientific analysis concerns with the respective investigator(s). Modification of proposal designs and related matters will be processed continually with investigators and the SRB until all SRB requirements have been met or materials are withdrawn. For all SRB/SRP actions and processes, ORA assigned staff will provide requisite tracking systems and maintain pertinent records in ORA for SRP minutes, official correspondences, and official files of relevant materials.

f. After successful SRB review and approval, the final version of the respective human research protocol can be submitted by the Director/NMRCD-OIC to ORA for IRB review and follow-on action. No materials can be received by ORA for IRB consideration without

AUG 16 2002

documented SRB review and approval. Documentation of the SRB review and approval must be submitted with the human research protocol including copies of all scientific review comments and results with investigator or Directorate responses as applicable for each case.

g. ORA will be responsible for adding the requirements of this directive into enclosure (1) of reference (f).

h. The Command will notify Walter Reed Army Institute of Research (WRAIR) of these matters so as to modify current Memorandum of Agreement arrangements for scientific review of joint human research efforts. The NMRC Command will ensure that NMRC SRB review will suffice for those efforts for which the NMRC IRB will serve as lead ethical review agent.

i. For all human use protocols that are to be accomplished as cross-agency research efforts among the NMRC Echelon 3 and 4 laboratories, the responsibility for scientific review will be assumed by that activity to whom lead IRB status for ethical review, approval, and oversight is to be assigned. However, an individual Echelon 4 activity may request NMRC SRB review and approval for various circumstances.

j. Echelon 4 activities are to ensure that internal human research reviews include scientific review and approval prior to IRB consideration.

6. Action. The NMRC SRB will be formally constituted and begin service on 01 October 2002 with all personnel complying with SRB review and approval actions on that same date.



R. B. OBERST

Distribution:
List(s) A, B, C and D