



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

IN REPLY REFER TO:
NAVMEDRSCHCENTINST 3900.4A
025
MAR 13 2008

NAVMEDRSCHCENTER INSTRUCTION 3900.4A

From: Commanding Officer, Naval Medical Research Center

Subj: SCIENTIFIC REVIEW FOR HUMAN RESEARCH PROTOCOLS

Ref: (a) 32 CFR Part 219
(b) DoD Directive 3216.2
(c) SECNAVINST 3900.39D
(d) NAVMEDRSCHCENTINST 3900.39C

Encl: (1) Scientific Review Checklist for Human Research
Protocols

1. Purpose. To establish a comprehensive Scientific Review Board (SRB) for scientific review of human research protocols for the Naval Medical Research Center in accordance with the requirements found in references (a) through (d).

2. Cancellation. NAVMEDRSCHCENINST 3900.4 is hereby cancelled and superseded.

3. Scope. This instruction applies to all research involving human beings, human specimens or human data being conducted by NMRC personnel, using DoD/DoN funding and/or conducted at DoD/DoN sites.

4. Responsibility. The Office of Research Administration (ORA) is directed with responsibility for providing administrative support to the SRB. The ORA will work closely with the SRB Chair to establish policies and prepare standard operating procedures.

5. SRB Membership.

a. 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 scientist to serve as the Vice Chair as appropriate.

b. The SRB will be composed of an ad hoc panel of personnel who qualify as principal and/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 the SRB Chair and the Scientific Directors for their respective personnel. Within NMRC, SRB Membership includes military, government civilians, Intergovernment Personnel Act (IPA) employees, and grant and contract personnel.

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

6. Procedures and Related Matters.

a. Scientific review and approval are required of all human research protocols and related materials prior to submission to ORA for Institutional Review Board (IRB) consideration.

b. Per reference (d), all investigators are required to forward all human research protocols and related materials through their regular chain of command to ORA for SRB consideration. ORA will log and forward those materials to the SRB Chair for review.

c. Upon receipt of materials requiring SRB review and approval, the SRB Chair will contact pertinent Directors to determine which persons would be most appropriate to perform scientific review. From the ad-hoc panel of personnel, the SRB Chair will appoint and convene a Scientific Review Panel (SRP) within three (3) business days of receipt of materials from ORA.

d. Each SRP will be composed of not less than three (3), but no more than five (5) members with one designated as the 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 investigator(s).

e. Each SRP will be required to complete its review within ten (10) working days from the time the SRB Chair names and convenes the SRP.

f. Each panel will be required to consider and document the following general criteria for scientific review:

(1) Significance. Is the research innovative? Is there military relevance to the research? Does this study address a problem of scientific and/or practical importance? Does the protocol adequately outline the scientific issues, define the underlying basic research and explain how the project will be a significant addition to the body of knowledge?

(2) Rationale/Approach & Design. Are there appropriate references or Standard Operating Procedures (SOP) to ensure that research assays will generate valid data? Is there accurate thoroughness of the investigator's evaluation of the relevant literature or discussion of previous studies (if available)? Is the statistical analysis plan reasonable and detailed (when appropriate)? Is there a description of the data analysis plan with appropriate statistical tests? Is there a rationale for the proposed number of subjects and, where appropriate, are there details of how missing data will be addressed? Are the conceptual framework, design, methods and analyses adequately developed, well-integrated and appropriate to the aims for the study? Does the Investigator acknowledge potential problem areas and consider alternative course(s) of action? Is data analysis plan consistent with the study objectives?

(3) Investigator. Is the investigator appropriately trained to conduct this study? Is the work proposed appropriate to the experience level of the principal investigator and associates? Are adequate measures described in the protocol to minimize investigator bias?

(4) Environment. Does the scientific environment in which the study will be done contribute to the probability of success? Does the proposed study take advantage of the unique features of the scientific environment or employ useful collaborative arrangements? Are the facilities appropriate?

g. The SRP will make one of the following recommendations concerning the research:

(1) Approve as submitted. The research requires no changes and is scientifically sound in its current condition.

(2) Modifications required to secure approval. The Panel requires changes to the research protocol and related documents that must be returned to the panel for final consideration and recommendation of approval.

(3) Disapprove. This research protocol as submitted is not scientifically sound and is not to be conducted in humans. A completely new protocol is necessary for consideration.

h. The SRP Coordinator will report written panel results directly to the SRB Chair. Enclosure (1) is provided for this purpose. The SRB Chair will submit results to ORA for dissemination to Investigators. It will be the responsibility of each Investigator to address any needs or scientific analysis concerns.

i. Modification of proposal designs and related matters will be processed continually with investigators and the SRP until all scientific requirements have been met or materials are withdrawn.

j. For all SRB/SRP actions and processes, ORA will provide requisite tracking systems and maintain pertinent records of scientific determinations, official correspondences, and official files of relevant materials.

k. After successful SRB review, the SRB Chair will send a final email to ORA approving the research protocol. ORA will notify the Investigator of the scientific approval. This notification along with any other communication should be kept in the Investigator's file as well as in the Command ORA files.

l. For all human research protocols that are to be accomplished as cross-agency research efforts among the NMRC Echelon 5 and 6 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.

m. Echelon 5 and 6 activities are to ensure that internal human research reviews include scientific review and approval prior to IRB consideration in compliance with references (a) through (c) and their respective DoD Navy Assurances.



J. C. DANIEL

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



HRPP#:

Scientific Review Checklist for Human Research Protocols

Date:

Reviewer (name):

Title of Project:

NMRC/NMRC Lead Investigator (name):

Principal Investigator, if different from above (name):

Part A – Significance

Please verify that the investigator has provided adequate information in the following areas:

	Yes	No	NA
a. Is the research innovative?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Is there military relevance to the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Does this study address a problem of scientific and/or practical importance?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Does the protocol define the underlying basic research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Does the protocol explain how the project will be a significant addition to the body of knowledge?			
f. Other (please describe)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments or Concerns:

Part B – Rationale/Approach & Design

	Yes	No	NA
a. Is there a clearly stated hypothesis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Is the number of objectives reasonable such that the scope of research is appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Are the research procedures adequately defined and are they valid?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Does the strength of the scientific design and methodology support the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Do the endpoints (i.e. methods, data collection) match the objectives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Are adequate measures described in the protocol to minimize investigator bias?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Are there appropriate references or SOPs to ensure that research assays will generate valid data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Is the investigator's evaluation of the relevant literature or discussion of previous studies (if available) thorough and accurate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Are the proposed methods and assays appropriate for the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Is the statistical analysis plan reasonable and detailed (when appropriate)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k. Is there a description of the data analysis plan with appropriate statistical tests? (The data analysis plan should be consistent with the study objectives.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l. Are the conceptual framework, design, methods and analyses adequately developed, well-integrated and appropriate to the aims for the study?			
m. Does the Investigator acknowledge potential problem areas and consider alternative tactics?			
n. Is data analysis plan consistent with the study objectives?			
o. Is there rationale for the proposed number of subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p. Where appropriate, are there details to explain how missing data will be addressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
q. Other (please describe)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments or Concerns:

Part C – Investigator

	Yes	No	NA
a. Is the investigator appropriately trained to conduct this study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Is the work proposed appropriate to the experience level of the principal investigator and associates?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Other (please describe)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments or Concerns:

Part D – Environment

I have personally reviewed:	Yes	No	NA
a. Does the scientific environment in which the study will be done contribute to the probability of success?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Does the proposed study take advantage of the unique features of the scientific environment or employ useful collaborative arrangements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Are the facilities appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Other (please describe)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments or Concerns:

Part E – Reviewer Recommendation

Recommended SRB Action (check one):

- Approve as submitted**
- Modifications required to secure approval described below**
- Disapprove for the reasons described below**

Comments or Concerns:

Signature of Reviewer

Date

Signature of SRB Chair

Date