



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

IN REPLY REFER TO:

NAVMEDRSCHCENINST 3900.4B
1U6G
11 MAY 2012

NAVMEDRSCHCEN INSTRUCTION 3900.4B

From: Commanding Officer, Naval Medical Research Center

Subj: SCIENTIFIC REVIEW FOR HUMAN RESEARCH PROTOCOLS

Ref: (a) 32 CFR 219
(b) DoD Instruction 3216.02
(c) SECNAVINST 3900.39D
(d) NAVMEDRSCHCENINST 3900.6D

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

1. Purpose. To establish a comprehensive Scientific Review Board (SRB) and process for scientific review of human research protocols for the Naval Medical Research Center (NMRC) per references (a) through (d).

2. Cancellation. NAVMEDRESCHCENINST 3900.4A is hereby cancelled and superseded.

3. Scope. This instruction applies to all research that has been determined to meet the definition of human subject research. This includes 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 Head, ORA will work closely with the SRB Chair and/or Vice Chair to establish policies and prepare Standard Operating Procedures (SOPs).

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 permanent Vice Chair as appropriate.

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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, Intergovernmental 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 will take place prior to submission for IRB consideration.

b. 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 or Vice Chair for review.

c. In the event the Chair and Vice Chair are conflicted or unavailable to serve, ORA will serve as the liaison to facilitate the review process and avoid a conflict of interest. Where an approval signature is required during this time, the Executive Officer (XO) will be the signatory.

d. Upon receipt of materials requiring SRB review and approval, the SRB Chair or Vice Chair will contact pertinent Directors to determine which persons would be most appropriate to perform scientific review. From the suggested list of panelist, the SRB Chair or Vice Chair will appoint and convene a Scientific Review Panel (SRP) within three (3) business days of receipt of materials from ORA.

e. Each SRP will be composed of not less than two (2), 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 research team.

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

g. 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 to the body of knowledge?

(2) Rationale/Approach and Design. Are there appropriate references or SOPs 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 mission 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.

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(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 or Vice Chair. Enclosure (1) is provided for this purpose. The SRB Chair or Vice Chair will submit results to ORA for dissemination to Investigators. It will be the responsibility of the Principle 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 or Vice Chair will send a final determination 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 review. The scientific review and approval must be

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submitted to the IRB for consideration per references (a) through (d) and their respective DoD Navy Assurances.

A handwritten signature in black ink, appearing to read "R. L. Haberberger, Jr.", with a long, sweeping underline.

R. L. HABERBERGER, JR.

Distribution:
NMRC Intranet



HRPP#:

Scientific Review Checklist for Human Research Protocols

Date:

Reviewer (name):

Department/Title:

Title of Project:

Navy 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. What is the military relevance to the research? Is it stated clearly in the protocol? Indicate location.	<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? If not, what is the rationale for the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Summarize the primary objective of the research (or indicate location in protocol)?			
c. Are the number of objectives reasonable such that the scope of research is appropriate?			
d. Are the research procedures adequately defined and are they valid?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Does the strength of the scientific design and methodology support the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Do the endpoints (i.e. methods, data collection) match the objectives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Are adequate measures described in the protocol to minimize investigator bias?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Are there appropriate references or SOPs to ensure that research assays will generate valid data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. 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"/>
j. What are the proposed methods and assays? Are they appropriate for the research (or indicate location in protocol)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k. What is the statistical analysis plan (or indicate location in protocol)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l. Is it reasonable and detailed (when appropriate)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

m. 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"/>
n. Are the conceptual framework, design, methods and analyses adequately developed, well-integrated and appropriate to the aims for the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o. Does the Investigator acknowledge potential problem areas and consider alternative tactics?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p. Is data analysis plan consistent with the study objectives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
q. What is the rationale for the proposed number of subjects (or indicate location in protocol)?			
r. Where appropriate, are there details to explain how missing data will be addressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
s. 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?			
c. Other (please describe)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments or Concerns:

Part D – Environment

	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?			
d. Other (please describe)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments or Concerns:

Part E – Questions/Comments for PI to Address

Following are the Scientific Reviewer comments which require the PI's response:

- 1.
- 2.
- 3.

Part F – 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