



DEPARTMENT OF THE NAVY
OFFICE OF NAVAL RESEARCH
800 NORTH QUINCY STREET
ARLINGTON, VA 22217-5660

IN REPLY REFER TO
ONRINST 3900.34B
ONR 34
13 July 2004

ONR INSTRUCTION 3900.34B

From: The Chief of Naval Research

Subj: PROTECTION OF HUMAN SUBJECTS

Ref: (a) DHHS Code of Federal Regulations Title 45, Part 46,
Protection of Human Subjects as amended
(b) DoD Common Rule Publication, 32 CFR 219 as amended
(c) DoD Directive 3216.2 Protection of Human Subjects
and Adherence to Ethical Standards in DoD-Supported
Research
(d) SECNAVINST 3900.39C
(e) BUMEDINST 3900.6B

Encl: (1) Office of Naval Research (ONR) Single Project Assurance
(SPA)

1. Purpose. To provide revised guidance and assign specific responsibilities for compliance with provisions contained in references (a) through (d), in grants, contracts, cooperative agreements, agreements under 15 U.S.C. Section 3710a Cooperative Research and Development Agreements (CRADAs), and other transactions that include the use of human subjects. The responsibility for appropriate protection of human subjects used in research lies with the proposing organization. The proposing organization's Institutional Review Board (IRB) is responsible for the initial and annual review of protection of human subjects' protocols. The proposing Institution is responsible for providing documentation of a Multiple Project Assurance (MPA) or Federal Wide Assurance (FWA) and copies of IRB approval letters/approved informed consent forms with research proposals.

2. Cancellation. ONRINST 3900.34A. This instruction has been extensively rewritten and should be read in its entirety.

3. Scope. This instruction applies to all Office of Naval Research (ONR) sponsored research and development efforts involving human subjects.

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4. Action. Addressees are required to comply with the policies stated in references (a) through (d). Specific action is required as follows:

a. ONR Program Officers are responsible for:

(1) Ensuring that the Principal Investigators (PIs), prior to their awards, submit the following required Human Protection approval documentation:

(a) IRB Approval Letter

(b) Appropriate Institutional Assurance Document (such as an FWA or MPA)

(c) Informed Consent Form

(2) Reviewing proposals for research grants, contracts, cooperative agreements, CRADAs and other transactions involving use of humans for:

(a) The merits of the requirement and soundness of the experiment, demonstration, and scientific approach.

(b) The adequacy of the proposal, including all required enclosures, submitted by the PI and Institution for conducting the experiment or demonstration.

(3) Devoting a portion of each site visit to review Human Protection. Any adverse finding shall be reported immediately to the ONR Special Assistant for Human and Animal Use.

b. ONR Human Systems Science and Technology Department (Code 34) is responsible for:

(1) Designating a Special Assistant for Human and Animal Use who will be the ONR "point of contact" for Human and Animal use issues and be responsible for review and action on investigations requiring ONR approval.

(2) Designating a Program Administrator who is responsible for:

(a) Ensuring the appropriate ONR web page <http://www.onr.navy.mil> regarding Human-Use requirements is accurate and current.

(b) Maintaining records of performer FWA or MPA assurances, IRB approval letters, informed consent letters, and subsequent annual review letters.

(c) Maintaining all records relating to human use issues.

c. The Contracts and Grants Division, Code 25, and in the case of CRADAs the ONR Product Innovation Division, Code 36, in compliance with references (a) through (d), is responsible for ensuring that award documents ("award documents" as used herein includes all grants, contracts, cooperative agreements, and other transactions) for research, involving the use of human subjects, identified by the ONR Program Officer, comply with the procedures set forth below:

(1) Ensuring that applicable clauses pertaining to use of human subjects are incorporated into the grant, contract, cooperative agreement or other transaction.

(2) Verifying prior to award execution that the award recipient has submitted to the ONR Program Officer, and that the contract file contains copies of all appropriate human subject compliance documents, which may include: approval of the IRB, approved consent forms, and Institutional Assurances of compliance, such as an MPA or an FWA.

(3) Forwarding all award packages pertaining to research using Human Subjects to ONR's Office of Counsel for review of legal sufficiency, regardless of dollar value associated with the proposed award, and shall not be executed until approved by the Office of Counsel.

d. Counsel is responsible for advising the ONR Contracts and Grants Division, Program Officers, the Special Assistant for Human and Animal Use, and all other ONR personnel regarding compliance with ONR human-use policy and all applicable legislation, regulations, directives, instructions and policy guidance.

5. ONR-Sponsored Research Conducted by Naval Activities or Personnel will comply with the provisions contained in references (a) through (d) and additional guidance described in reference (e).

6. Single Project Assurances. On rare occasions in which an Institution does not have an MPA or FWA on file with the Office for Protection of Research Risks (OPRR), Department of Health and Human Services, or a DoD component activity, a Single Project Assurance

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Services, or a DoD component activity, a Single Project Assurance (SPA) may be issued by ONR. This SPA must comply with the format provided in enclosure (1) and be approved by the Program Officer and the Special Assistant for Human and Animal Use. Once these requirements have been satisfied, the Special Assistant will assign an ONR SPA assurance number.



JAY M. COHEN
Rear Admiral, U.S. Navy

Distribution:
ONR All Hands (via electronic mail)

ONR SINGLE PROJECT ASSURANCE (SPA)

NOTE: THIS IS AN ONR SINGLE PROJECT ASSURANCE (SPA) FOR AN INSTITUTION WHICH CURRENTLY DOES NOT HAVE A MULTIPLE PROJECT ASSURANCE (MPA) ON FILE WITH OPRR OR DOD COMPONENT ACTIVITY

FULL BOARD REVIEW REQUIRED OF IRB

Using this Sample, type on Organizational Letterhead supplying where indicated, information specific to the proposed research activity and your Organization, including the required certification on the endorsement page.

(Name of Institution)

***Assurance of Compliance with DoD Regulations for
Protection of Human Research Subjects***

PART 1

(Name of Institution), hereafter known as the "institution", hereby gives assurance that it shall comply with the Department of Defense (DoD) Regulations for the Protection of Human Research Subjects, Title 32, Code of Federal Regulations, Part 219 (32 CFR 219) revised as of July 1, 1993, as specified below.

I. Statement of Principles and Policies

A. Ethical Principles

1. This institution is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report"). In addition, the requirements set forth in 32 CFR 219 shall be met for all applicable DoD-supported research.

B. Institutional Policy

1. Except for research in which the only involvement of human subjects is in one or more of the categories exempted or waived under 32 CFR 219.101(b)(1-6) or 219.101(e) of the DoD regulations, this policy is applicable to all research involving human subjects, and all other activities which even in part involve such research, if either:

a. the research is sponsored by this institution, or

b. the research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or

c. the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or

d. the research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

2. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects or research covered by this policy.

3. This institution assures that before human subjects are involved in research covered by this policy, proper consideration shall be given to:

a. the risks to the subjects,

b. the anticipated benefits to the subjects and others

c. the importance of the knowledge that may reasonably be expected to result, and

d. the informed consent process to be employed.

4. This institution acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this policy.

in a manner and method which meets the requirements of 32 CFR 219, and in cases of research involving protected classes of individuals 45 CFR 46, Subparts B, C, and D.

D. The IRB shall review, and have the authority to approve, require modification in, or disapprove changes proposed in this research activity.

E. The next scheduled meeting of the IRB for review of this activity shall be (insert date no later than one year from last review). The IRB may be called into an interim review session by the Chairperson at the request of any IRB member or Institutional Official to consider any matter concerned with the rights and welfare of any subject.

F. The IRB shall prepare and maintain adequate documentation of its activities in accordance with 32 CFR 219.115.

G. The IRB shall report promptly to institutional officials and the appropriate Service Oversight Office:

- a. any serious or continuing noncompliance by investigators with the requirements of the IRB, and
- b. any suspension or termination of IRB approval.

H. The IRB shall report promptly to institutional officials any information received concerning:

- a. injuries to human subjects,
- b. unanticipated problems involving risks to subjects or others, and
- c. any changes in this research activity which are reviewed and approved by the IRB.

II. Research Investigator Reporting Responsibilities

A. Research investigators shall report promptly to the IRB proposed changes in this research activity and the changes shall not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects.

B. Research investigators shall report promptly to the IRB any unanticipated problems involving risks to subjects and others.

II. I certify that this institution endorses the above project and abides by the principles, policies, and procedures of Parts 1 and 2 of this Assurance of Compliance.

Authorized Institutional Official

Signature _____ Date _____
Name and Title _____
Institution Address _____

Phone Number _____

SPACE BELOW FOR DOD/SERVICE USE

III. All parts of this Assurance are in compliance with the requirements of Part 219, Title 32 of the Code of Federal Regulations.

Service/DOD Approving Official

Signature _____ Date _____
Name and Title _____
Institution Address _____

Phone Number _____

ASSURANCE NO. _____

SAMPLE
INSTITUTIONAL REVIEW BOARD (IRB) MEMBERSHIP

NAME OF IRB AGENCY OR COMMAND _____

Address and Phone No Chairperson only _____

Members' Names First MI Last	Highest Degree Earned	Scientific Specialty	Affiliation with Institution (Yes or No)
(1)			
(2)			
(3)			
(4)			

- (1) Denotes Chairperson
- (2) Denotes IRB members
- (3) Denotes IRB alternates to member
- (4) Denotes non-voting IRB attendee (expert or technical expertise)