



DEPARTMENT OF THE NAVY

BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-5300

IN REPLY REFER TO
BUMEDINST 3900.6B CH-1
BUMED-26H
10 Jan 2002

BUMED INSTRUCTION 3900.6B CHANGE TRANSMITTAL 1

From: Chief, Bureau of Medicine and Surgery
To: All Naval Research Activities

Subj: PROTECTION OF HUMAN SUBJECTS

Encl: (1) Revised page 9

1. Purpose. To permit authorization of the use of expedited review procedures in local Protection of Human Subjects Programs.
2. Action. Remove page 9 and replace with enclosure (1).
3. Retain. For record purposes, keep this change transmittal in front of the basic instruction.


D. C. ARTHUR
Deputy

Available at: <http://navymedicine.med.navy.mil/instructions/external/external.htm>

(1) Simultaneous assignment of an individual to membership on both the Scientific Review Committee and the IRB should be minimized to the greatest extent possible.

(2) The purpose and function of the IRB will not be combined with the purpose and function of a Scientific Review Committee.

(3) The IRB may make recommendations generally considered to fall within the purview of the Scientific Review Committee if these recommendations pertain to considerations for the protection of research participants.

d. It is the responsibility of the IRB and the IRB chair to ensure research protocols are reviewed and evaluated in strict compliance with all elements of pertinent laws, regulations, and guidance, and to establish a timetable for submission and review of research protocols.

(1) If a principal investigator submits a protocol for review and requests action from the IRB in less than the routinely allotted time, the principal investigator will provide justification for the request. The IRB chair may accept the submission for special review, or deny the request for special handling and treat the protocol as a routine submission. The principal investigator will be informed of the decision.

(2) If the IRB cannot complete action on a protocol in the time allotted, the IRB will inform the principal investigator of the reason for the delay and the expected completion date.

(3) The principal investigator and IRB chair will provide copies of the request for special handling, decision on the special handling request, and notification of delay in completion of IRB action to the convening authority.

e. Expedited review, as defined in paragraph 5q of reference (b), may be locally implemented only with specific written authorization from the Special Assistant for the Protection of Human Subjects, Bureau of Medicine and Surgery (MED-26H). Requests for approval of local expedited review authority should be submitted via the chain of command to MED-26H. (R)

f. No member of the IRB will vote upon or participate in the review of a research protocol in which he or she is materially involved or has a conflict of interest. Material involvement or conflict of interest includes managerial or leadership responsibility for the research protocol under review, principal or co-investigator status, or other conflicts of interest as determined by regulation or by the convening or approving authority. Persons with conflicts of interest may only be present at meetings during the time they are providing information requested by the IRB. Presence during the discussions or deliberations of the IRB is not authorized.

g. If the IRB convening or approving authority for a research protocol is involved as a principal or co-investigator for the protocol, or if any other conflict of interest exists, that individual is disqualified from taking official action. The protocol and all pertinent documents will be forwarded to the next higher echelon in the chain of command for action, along with a statement indicating the reason for disqualification.