



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

IN REPLY REFER TO:

3900

Ser 00R/1154

JUN 14 2001

MEMORANDUM OF AGREEMENT
BETWEEN
COMMANDING OFFICER, NAVAL MEDICAL RESEARCH CENTER
AND
COMMANDER, WALTER REED ARMY INSTITUTE OF RESEARCH

Subj: PROVISIONS FOR ETHICAL REVIEW OF COLLABORATIVE HUMAN
USE PROTOCOLS

Ref: (a) 32 CFR 219
(b) DoD Directive 3216.2
(c) Memorandum of Understanding between Bureau of
Medicine and Surgery (BUMED) and Human Subjects
Research Review Board (HSRRB) of 12 November 2000.

1. Purpose. The purpose of this agreement is to provide appropriate ethical review of human use protocols while avoiding duplicative review for all efforts on which Naval Medical Research Center (NMRC) and Walter Reed Army Institute of Research (WRAIR) investigators, including those assigned to NMRC and WRAIR subordinate activities, participate collaboratively.

2. Background

a. Under the authority and direction of references (a) and (b), the Office of the Surgeon General of the Navy and the Office of The Surgeon General of the Army each have distinct responsibilities that may not be abrogated or decreased for the protection of the rights and welfare of human subjects from research risks. These responsibilities, including the final responsibility for the ethical review and approval of human use research protocols, have been developed into separate, agency-specific requirements and regulatory documents. Authority to conduct ethical review and approval of human use protocols has been delegated to the local level by the respective Surgeons General.

b. Under the authority of references (a) and (b), and as granted by their respective Surgeons General, NMRC and WRAIR each hold valid Department of Defense (DoD) assurances for the protection of human subjects.

c. In addition, for efforts involving Department of Health and Human Services (DHHS) sponsored research, both institutions hold Federal Wide Assurances for the protection of human subjects issued by the Office for Human Research Protections (OHRP).

d. Under the assurances of their respective Surgeons General, NMRC and WRAIR have established duly constituted systems for review and approval authorities per paragraph 6.2 of reference (b).

e. Since NMRC and WRAIR scientists often engage in cooperative research efforts involving human subjects, this agreement establishes terms and provisions consistent with the authoritative norms found in reference (b) and the initiatives found in reference (c) for the reciprocal acceptance of each command's IRB review authority while maintaining separate approval authorities as appropriate and required. This agreement is made in compliance with paragraph 114 of reference (a) so as to reduce duplication of effort but without resigning the responsibility of either service for the ethical protection of the rights and welfare of human subjects from research risks. This agreement applies to all intramural DoD human use research protocols on which researchers assigned to NMRC, WRAIR and their subordinate activities are named together as investigators (NMRC-WRAIR human use protocols).

3. Terms and Provisions. The following are the terms and provisions for NMRC-WRAIR human use protocols:

a. Each service will maintain its separate approval authority; and signatures from both approval authorities will be supplied to approval documents regarding NMRC-WRAIR human use protocols pertinent to this agreement.

b. For all intramural (in-house DoD) NMRC-WRAIR human use protocols, both institutions will accept assignment to one IRB review. IRB assignment will be based upon Paragraph 5.3.2.2.2 of reference (b), namely the duty assignment of the Principal Investigator or the duty assignment of the principal submitting investigator when the Principal Investigator is a third party scientist.

c. For the sake of clarification, for all intramural (in-house DoD) NMRC-WRAIR human use protocols, only one researcher will be named as Principal Investigator. However, special circumstances, such as multiple agency efforts where one agency

is non-Army/non-Navy, may require greater specificity. In such cases, the decision as to which IRB system will be used will be made jointly by the NMRC Office of Research Administration (ORA) and the WRAIR Office of Research Management (ORM).

d. For all NMRC-WRAIR human use protocols, scientific review is required and must be accomplished prior to IRB consideration. For protocols being accomplished at NMRC and WRAIR headquarters, scientific review will be provided by WRAIR with the NMRC Commanding Officer giving permission to WRAIR for the assignment of qualified NMRC scientists to assist with the increased workload for the WRAIR scientific review committee. WRAIR scientific review can also include acceptance of scientific reviews from sister United States Army Medical Research and Materiel Command (MRMC) institutions and the Armed Forces Research Institute of Medical Sciences (AFRIMS), if appropriate. For NMRC-WRAIR human use protocols where primary IRB review responsibility will be assigned to NMRC Echelon 4 activities, scientific review will be provided in those locations. For the sake of consistency and to maintain the highest level of scientific review possible, this review must consist of a committee review such as that accomplished by the WRAIR scientific review committee.

e. For all NMRC-WRAIR human use protocols, investigators of one agency will be required to comply with the submission of additional items as may be required by the other institution to fulfill service-specific requirements (e.g. documentation of completion of GCP training, documentation related to physician credentialing etc).

f. Regarding service-specific differences in ethics standards for the protection of human subjects, stricter interpretations will always take precedence. This does not apply, however, to permissible administrative procedures for review (e.g. WRAIR usage of expedited review).

g. In the case of conflicting regulations, harmonization and amelioration will be the joint responsibility of the NMRC and WRAIR IRB Chairpersons, NMRC-ORA and WRAIR-ORM.

h. Each institution will delegate authority for the executive administration of this agreement to NMRC-ORA and WRAIR-ORM working in collaboration.

4. Effective Date and Review. This agreement will become effective upon the signature of both authorities and will be

evaluated at least yearly by both parties for revision, updating or amendment. The agreement may be cancelled at any time by either party.

Signed

Signed



REPLY TO
ATTENTION OF
MCMR-UWZ-C (5-14a)

DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, D.C. 20307-5100

MEMORANDUM FOR RECORD

SUBJECT: Modification to the Memorandum of Agreement (MOA) between the Naval Medical Research Center (NMRC) and the Walter Reed Army Institute of Research (WRAIR) Dated 14 June 2002

The purpose of this modification is to acknowledge the establishment of the NMRC and Echelon 4 Commands' Scientific Review Boards (SRB), and to amend the existing MOA between NMRC and WRAIR (Dated 14 June 2002), which outlines scientific review requirements and procedures.

For those protocols which are covered under the MOA for which NMRC is the lead agency, the newly constituted NMRC SRB and Echelon 4 Command SRBs, will be responsible for providing scientific review. NMRC Office of Research Administration (ORA) will supply the WRAIR Office of Research Management (ORM) with all related documentation pertaining to scientific review.

This modification also acknowledges the acceptance of scientific reviews performed by Army Medical Research Materiel Command (MRMC) sister institution scientific review committees (SRC). The WRAIR ORM will supply the NMRC ORA with any documentation pertaining to scientific reviews performed by MRMC sister institutions.

All other terms and provisions from the original MOA outlining the process for ethical review and approval of human subjects research remain the same. This modification will become effective upon the signature of both directors of the research administration offices and the signatures of both institutional authorities.

Signed

Signed