



DEPARTMENT OF THE ARMY  
WALTER REED ARMY INSTITUTE OF RESEARCH  
WALTER REED ARMY MEDICAL CENTER  
WASHINGTON DC 20307-5001

REPLY TO  
ATTENTION OF

MCMR-UWZ-C

1 September 2006

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: New Review and Approval Process for Human Subjects Research Protocols Conducted by Personnel from WRAIR and/or its Detachments, U.S. Army Dental Research Detachment, USAMRD Brooks AFB (Laser Research Detachment), USAMRU-Europe, AFRIMS and USAMRU-Kenya (Effective: 1 September 2006)

1. Effective 1 September 2006, unless otherwise specified in an Institutional Review Board (IRB) Agreement (IAA), the Walter Reed Army Institute of Research (WRAIR) Human Use Review Committee (HURC) will serve as the IRB of Record for WRAIR and its detachments, the U.S. Army Dental Research Detachment, USAMRD Brooks AFB (Laser Research Detachment), USAMRU-Europe, AFRIMS and USAMRU-Kenya. The WRAIR HURC is the designated IRB in the DOD Multiple Project Assurances of Compliance for Protection of Human Research Subjects for these organizations. This change ensures WRAIR, AFRIMS and USAMRU-K will conduct research in compliance with Federal, DOD and Army human subjects protection requirements. Please note that there will always be a requirement for host country IRB approval of OCONUS protocols.
2. On 13 April 2006, the Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC), approved a significant change in the USAMRMC headquarters (HQ) human subjects research review and approval procedures that will streamline the human subjects protection processes in the Command. This change allows for the USAMRMC HQ Office of Research Protections (ORP), Human Research Protection Office (HRPO) administrative review and approval of greater than minimal risk (GTMR) studies. Prior to 1 September 2006, the process required that all GTMR human subjects research protocols undergo review and approval by the Human Subjects Research Review Board (HSRRB) at USAMRMC HQ. With this change, the HSRRB review will be reserved for studies that meet a high risk profile or are referred to the HSRRB by the Deputy, ORP or designee.
3. The HSRRB will still perform a full board review of protocols that include: "first in humans" investigational new drugs (INDs), gene transfer studies, non-lethal weapons, INDs with high toxicity profiles, serious non-compliance issues, and special categories of protocols to be determined by ORP HRPO on a case by case basis.
4. This change in process modifies how WRAIR CONUS and OCONUS GTMR studies are reviewed. The WRAIR HURC will review protocols prior to submission for the ORP HRPO for administrative review and approval.
5. Separate guidance will be issued explaining the specific processes to be followed; however, as of 1 September 2006, WRAIR investigators who intend to work on a human

MCMR-UWZ-C

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subjects research protocol are to submit all new protocols to the Office of Research Management (ORM) for review by the WRAIR Human Use Review Committee (HURC) at [ResearchManagement@na.amedd.army.mil](mailto:ResearchManagement@na.amedd.army.mil). A combined USAMRMC ORP HRPO and ORM pre-review of greater than minimal risk protocols will be performed to ensure compliance with the appropriate regulatory requirements, to assure that the process maintains its efficiency, rigor and effectiveness, and to fulfill the DoD requirement for Headquarters-level review.

6. Please note: the Commander, WRAIR, remains the final implementation authority for all protocols involving WRAIR or its detachments (CONUS & OCONUS). This is required prior to the start of any research activity.

7. We appreciate your support during this time of transition. Please contact the Office of Research Management for any specific questions or guidance as to how this process will impact your protocols in development.

8. The point of contact for this action is Sara W. Rothman, Ph.D., Director, Office of Research Management, at (301) 319-9940 ([SR1@us.army.mil](mailto:SR1@us.army.mil)).

Signed - Kenneth A. Bertram

KENNETH A. BERTRAM

COL, MC

Commander

DISTRIBUTION:

All WRAIR Research Divisions

All Detachments of WRAIR (CONUS & OCONUS)

USAMRMC ORP

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DEPARTMENT OF THE ARMY  
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND  
504 Scott Street  
Fort Detrick, MD 21702-5012

REPLY TO  
ATTENTION OF:

MCMR-ZA

13 APR 2006

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: U.S. Army Medical Research and Materiel Command (USAMRMC) Second-Level Review of Human Subjects Research

1. This Memorandum implements a change to the process by which the USAMRMC Headquarters conducts second-level review of human subjects research. Currently, all extramural and Greater-Than-Minimal-Risk (GTMR) intramural human subjects research studies are required to be reviewed and recommended for approval by the USAMRMC Human Subjects Research Review Board (HSRRB). Prior to approval by the USAMRMC, these studies must also be approved by a local Institutional Review Board and undergo an in-depth pre-HSRRB review by highly-qualified USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO) Human Subjects Protection Scientists (HSPSs).
2. The USAMRMC ORP analysis of protocols submitted to the HSRRB during the period 2004-2005 supports the conclusion that second-level HSRRB review does not substantively increase the ethical protections afforded to subjects in lower-risk or routine GTMR studies, however it does add complexity to the process. The ORP review concluded that local Institutional Review Board review and approval coupled with the in-depth human subjects protection review provided by the ORP HSPSs are sufficient to ensure that the USAMRMC-managed research is compliant with Federal, DOD, Army and USAMRMC regulatory requirements. The ORP further concluded that the resources of the HSRRB should be reserved for review of specific categories of human subjects research that stand to benefit from an additional Command-level review by the HSRRB.
3. Accordingly, effective as of the date of this Memorandum:
  - a. The HSRRB will conduct second-level review of extramural and intramural research that is most likely to benefit from a Command-level HSRRB review. This includes research that involves:
    - (1) "First in humans" investigational new drugs (INDs), devices, biologics and vaccines.
    - (2) Gene transfer therapies.
    - (3) Non-lethal weapons.
    - (4) INDs with high toxicity profiles.
    - (5) Issues regarding non-compliance with human subjects protection regulations.

**MCMR-ZA**

**U.S. Army Medical Research and Materiel Command (USAMRMC) Second-Level Review of Human Subjects Research**

(6) Protocols determined by the Deputy, ORP and/or ORP HRPO designee(s) to require HSRRB review.

b. The USAMRMC ORP HRPO will conduct second-level review and protocol approval of all other categories of extramural and GTMR intramural human subjects research. The Deputy, ORP and/or ORP HRPO designee are authorized to approve these studies for implementation. The Deputy, ORP and/or ORP HRPO designee(s) retain the discretion to refer any research to the HSRRB for second-level review.

4. The purpose of this change is to streamline the human subjects research review and approval process without sacrificing rigor or effectiveness. This change in USAMRMC second-level human subjects protection review processes is fully compliant with Federal, DOD and Army human subjects protection review requirements.

5. The point of contact for this Memorandum is COL Laura R. Brosch, ORP, USAMRMC, at 301-619-7802, [laura.brosch@us.army.mil](mailto:laura.brosch@us.army.mil).

Signed - Eric B. Schoomaker

ERIC B. SCHOOMAKER  
MG, MC  
Commanding General

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