



DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
503 ROBERT GRANT AVENUE
SILVER SPRING, MD 20910-7500

REPLY TO
ATTENTION OF

MCMR-UWZ-C

5 March 2012

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: WRAIR Policy Letter 12-08, Final Approval Authorization for Human Subjects Research Protocol Implementation

1. References.

- a. Department of Defense (DOD) Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research, 20 October 2011
- b. 32 Code of Federal Regulation (CFR) 219, Protection of Human Subjects, 1 July 1999
- c. 21 CFR 50, Protection of Human Subjects and 21 CFR 56, Institutional Review Boards, 1 April 2003
- d. Army Regulation (AR) 70-25, Use of Volunteers as Subjects of Research, 25 January 1990
- e. ALARACT 031/2008, Army Human Subjects Protection Requirements, DTG 141557Z
- f. U.S. Army Medical & Materiel Command (MRMC) Command Policy, Requirements for Initial and Ongoing Education and Training in the Protection of Human Subjects in Research
- g. Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1979
- h. Human Research Protection Program (HRPP), Walter Reed Army Institute of Research (WRAIR), July 2008
- i. AR 70-41, International Cooperative Research, Development, and Acquisition
- j. Section 3701, Title 15, United States Code (USC), Chapter 63—Technology Innovation
- k. AR 70-57, Military-Civilian Technology Transfer

This Policy Letter supersedes WRAIR Policy 11-13, dated 7 April 2011.

l. WRAIR Policy 12-09, Determination that an Activity is Research Involving Human Subjects

m. WRAIR Policy 12-05, Submission of Protocols Involving Human Subjects, Human Specimens, and/or Human Data for Scientific and Ethical Review

n. WRAIR Policy 11-49, Initial and Ongoing Human Subjects Protection Education and Training Requirements

o. Command Policy Memo 2008-42, Clinical Trial Pre-Briefing Requirements

p. Office of The Surgeon General (OTSG)-Sponsored Investigational New Drug (IND) Submissions Requiring IRB Approval. The Division of Regulated Activities and Compliance, U.S. Army Medical Materiel Development Activity, 9 Jul 08

q. Memorandum for Record, Immediate Changes to WRAIR Policy Letter 11-13 and Associated Standard Operating Procedures, WRAIR Commander, 19 July 2011

2. History. This policy is being issued in accordance with WRAIR & USAMRMC requirements and is effective upon signature, superseding WRAIR Policy Letter 11-13. This version of the policy will remain in effect until amended or rescinded.

3. Purpose. This policy establishes the baseline requirements prior to issuance of the Walter Reed Army Institute of Research (WRAIR) Commander's authorization approval of a human subjects research protocol. The Commander, WRAIR has delegated authority to the Human Subjects Protection Branch (HSPB), to verify, via specific documentation, that these requirements have been met.

4. Definitions.

a. Research Involving Human Subjects. Any research that involves human subjects, identifiable human data, or identifiable human anatomical substances.

b. Engaged in Research. An institution is engaged in research if its employees (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes.

c. Institutional Official. Individual ultimately responsible for implementation of the DOD Assurance of Compliance for the Protection of Human Research Subjects and the associated Human Research Protection Program at an institution engaged in research

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involving human subjects. Within the USAMRMC, the Commander of the institution/organization engaged in research is the institutional official.

5. Background. This policy is in place to comply with Federal, DOD, Army, and MRMC regulatory requirements. The DOD Instruction 3216.02, Protection of Human Subjects, requires that awareness of human subjects protection requirements be established for all DoD personnel involved in the conduct, review, or approval of research involving human subjects. The DoD unique human subjects protection requirement occurs when the WRAIR Institutional Review Board (IRB) makes a recommendation for approval of a human subjects research study to the Commander. Based on the recommendation for approval, the Commander makes a final determination to grant authority to implement the human subjects study or makes a determination to not concur with the IRB's recommendation for approval. In circumstances where the WRAIR defers IRB review to another organization, the WRAIR Commander does NOT defer his/her responsibility and authority for authorization. A signed approval authorization memo is still required to implement human subjects research conducted by, or in collaboration with WRAIR.

a. The Commander, WRAIR will not issue an authorization of approval until ethical review(s) have been conducted at collaborating institutions (& approval/determinations are in hand), and funding has been identified.

b. Therefore, while WRAIR IRB approval records may be in place, initiation cannot occur until all of the following requirements have been addressed and met (when appropriate): a) business agreements are signed by all parties, c) the Commanding General's clinical trial briefing has been conducted (per MRMC Policy 2008-42), d) a final approval memo from the study Sponsor to initiate the study has been received, e) FDA 30-day waiting period has occurred. Note: This list is not all inclusive.

6. Applicability and Scope. This policy applies to all personnel employed by or affiliated with the WRAIR who conduct, review, approve, support, manage, or oversee research under the WRAIR Human Research Protection Program (HRPP).

Note: This also applies to contractors or partners who conduct human subjects research under the WRAIR HRPP.

7. Policy. No WRAIR investigators shall commence with any research activity on a human subjects research protocol, until an approval authorization memorandum is signed by the Commander, WRAIR, or his/her alternate approving authorities. This includes contacting, advertising to, recruiting, screening and/or enrolling subjects. This policy applies to categories of research to include: exempt, minimal risk, and greater than minimal risk studies, as per WRAIR Policy 12-09. Note: this also applies to studies

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in which WRAIR investigators are supporting in a peripheral capacity (ie. performing laboratory assays, data mining, etc.). Studies determined to be “research not involving human subjects” by the HSPB or the IRB Chair may also require certain elements be in place prior to initiation. Investigators are encouraged to seek guidance from the HSPB for this category of research.

8. Implementation. **Responsibility:** Pls (and/or WRAIR POCs) and Branch Directors/Detachment Commanders are responsible for ensuring required items are in place prior to implementation of a human subjects research protocol. Failure to do so will result in involvement of the Deputy Commander to rectify the deficiencies through the Branch Director/Detachment Commander. The Deputy Commander could intervene via multiple avenues including, but not limited to, poor performance review and/or disciplinary action.

9. Point of Contact. The point of contact for this action is the Deputy Commander, WRAIR, at (301) 319-9956.

Signature on File

RALPH L. ERICKSON
COL, MC
Commanding

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