



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

15 May 2014

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Walter Reed Army Institute of Research (WRAIR) Policy Letter 2014-26,  
Scientific Review Committee

1. REFERENCES:

- Department of Defense (DOD) Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research, November 2011.
- 32 Code of Federal Regulation (CFR) 219, Protection of Human Subjects.
- Army Regulation (AR) 70-25, Use of Volunteers as Subjects of Research, 25 January 1990.
- WRAIR Policy 12-05 Submission of Human Subjects Research Protocols.
- Guidance for Industry. Investigator Responsibilities: Protecting the Rights, Safety and Welfare of Human Subjects, October 2009.
- The Belmont Report: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research".

2. HISTORY:

This version replaces WRAIR Policy Letter 11-20 and is effective upon signature. This version of the policy will remain in effect until amended or rescinded.

3. PURPOSE:

The WRAIR will ensure proper scientific oversight of human subjects research protocols by establishing and maintaining a Scientific Review Committee (SRC), consisting of subject matter experts who will review the scientific merit of human subjects research protocols prior to or concurrent with review by the Institutional Review Board (IRB).

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#### 4. DEFINITIONS:

- *Engaged in Human Subjects 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. This includes any research that involves human subjects, identifiable human data, or identifiable human anatomical substances/specimens.
- *Human Research Protection Program (HRPP).* An integrated institution-wide program coordinated by the Human Subjects Protection Branch. The main purpose of a WRAIR-specific HRPP is to ensure that all of WRAIR's activities related to human subjects research are conducted in accordance with regulatory requirements and ethical principles as set forth in the Belmont Report. Major components of the HRPP include the IRB, several additional groups that provide research review, such as, the Office of Research Technology Applications (ORTA), Institutional Biosafety Committee (IBC), WRAIR Safety Office, the Scientific Review Committee (SRC), MRMC Human Research Protections Office (HRPO), and the WRAIR Translational Medicine Branch. Additional components include: assurances, regulations, policies, SOPs, investigators, sponsors, overseas detachment directors, MRMC headquarters, etc.
- *Principal Investigator (PI):* The individual who is responsible and accountable for conducting a human research study. This individual will have the appropriate scientific training and experience, as well as, the appropriate ethical training and experience, to assume full responsibility and accountability for the scientific integrity of the research data and results. The PI is responsible and accountable for designing, conducting, and monitoring a clinical study, and has access to the data. The PI, as the leader of the research team, assumes full responsibility for the treatment and evaluation of subjects, either directly or indirectly (designee of a healthcare provider). The PI may formally delegate roles and responsibilities to other members of the study team, as appropriate, but retains full responsibility for the conduct of all study activities. The PI is also responsible for protecting the rights and welfare of human subjects and is responsible for carrying out sound ethical research consistent with research plans in a protocol approved by a properly constituted IRB.
- *Protocol:* A document that describes the objective(s), design, methodology, statistical considerations, and organization of a research study. The protocol also describes the background and rationale for the study and the roles/responsibilities of the investigators. For a complete listing of required protocol documents, please see WRAIR Policy 12-05.

- *WRAIR Point of Contact (POC)*: An individual, affiliated with WRAIR or its detachments, who is responsible for submission of protocol documents to the Human Subjects Protection Branch (HSPB) over the lifecycle of the study as new protocol actions are processed. This individual remains in contact with the HSPB regarding the study as well as to regulatory authorities. This individual is generally the lead WRAIR investigator on the protocol, and may or may not be the overall study PI. The POC can be the PI, a clinical coordinator, program manager, associate investigator, or other individual involved in the study in a scientific or administrative capacity.

#### 5. APPLICABILITY:

This policy letter applies to WRAIR and its detachments compliance with the Standard Operating Procedure (SOP) UWZ-002 version 0.01 for the scientific review of human subjects research protocols. It is the responsibility of all investigators participating in the performance of human subjects research at the Institute and its detachments to comply with this SOP.

#### 6. POLICY:

The WRAIR only supports research involving human subjects when the project has been found by the WRAIR SRC to be in compliance with the U.S. federal government's "Common Rule" for the protection of human subjects, federal regulations, state/country laws, local and WRAIR/MRMC policies. Research is to be designed and conducted with the highest level of expertise and integrity. All research involving human subjects must include a review by the SRC. In general, protocol review by the SRC must be completed prior to submission to the IRB. However, the IRB may review a protocol still under SRC review if directed by the HSPB director and Science Director following their individual ad hoc reviews.

Investigators, Program Managers, Branch/Center Directors, and Detachment Directors must ensure that protocols submitted for SRC review are scientifically valid, feasible, appropriately resourced and meet the documentation requirements set forth in WRAIR Policy 12-05.

#### 7. POINT OF CONTACT:

The point of contact for this policy letter is the Science Director, Dr. Maryanne T. Vahey, at (301) 319-9916.

Signature on file at HSPB



STEVEN E. BRAVERMAN  
COL, MC  
Commanding