



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

21 October 2011

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: WRAIR Policy Letter 11-49, Initial and Continuing Human Subjects Protection Education and Training Requirements

1. REFERENCES:

- a. Department of Defense (DOD) Directive 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research, 24 April 2007
- 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 2010
- d. Army Regulation 70-25, Use of Volunteers as Subjects of Research, 25 January 1990
- e. Message, ALARACT 031/2008, Army Human Subjects Protection Requirements, DTG 141557Z February 2008
- f. United States Army Medical Research and Materiel Command (USAMRMC) Policy #2010-33, Requirements for Initial and Ongoing Education and Training in the Protection of Human Subjects in Research, dated 10 December 2010
- g. Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subject of Research, 1979
- h. Human Research Protection Plan, Walter Reed Army Institute of Research, 30 July 2008
- i. WRAIR Policy Letter 11-50, Determination that an Activity Is Research Involving Human Subjects
- j. Office for Human Research Protections (OHRP), Guidance on Engagement of Institutions in Human Subjects Research, dated 16 October 2008

This policy supersedes WRAIR Policy Letter #11-05, dated 25 March 2011.

2. HISTORY:

a. This Walter Reed Army Institute of Research (WRAIR) Policy Letter supersedes the previous WRAIR Policy Letters #11-05 (dated 25 March 2011) and # 08-07 (dated 3 July 2008). This version is effective 21 October 2011. This policy will remain in effect until amended or rescinded.

b. This policy is supplemental to United States Army Medical Research and Materiel Command (USAMRMC) Policy #2010-33 and is being issued in accordance with MRMC requirements.

3. PURPOSE:

a. This policy establishes the minimum requirements for initial and ongoing (continuing) human subjects protection (HSP) education and training for personnel employed by or affiliated with the Walter Reed Army Institute of Research (WRAIR) who conduct, review, approve, support, manage, or oversee research under the WRAIR Human Research Protection Plan (HRPP).

b. This policy also establishes the requirements for collaborating non-WRAIR investigators and research personnel where no alternate institutional training policy or program exists.

4. DEFINITIONS:

a. Consultant: An individual (who may be listed on the protocol as such) not associated with the human subjects research protocol, but who provides professional advice or training in a particular area of expertise such as study design or data analysis methods. The only data that they may review must be in aggregate form and only to provide advice or training. This individual must not have any contact with human subjects or identifiable human subjects' data or specimens. This may also include review of safety reports of research regulated by the U.S. Food and Drug Administration (FDA), as outlined in the Office for Human Research Protections (OHRP), Guidance on Engagement of Institutions in Human Subjects Research dated 23 October 2008.

b. Human Subjects Protection Branch (HSPB) Staff: The administrative support team for the WRAIR Institutional Review Board (IRB).

c. DOD Research Monitors: Research monitors are physicians, dentists, psychologists, nurses, other healthcare providers, or other professionals capable of overseeing the progress of research protocols, especially issues of individual subject/patient management and safety.

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Research monitors must be independent of the investigative team and possess sufficient educational and professional experience to serve as the subject/patient advocate.

d. Engagement in Human Subjects Research: An institution is engaged in human subjects research if its employees, for the purposes of the research project (i) obtain data about the subjects through intervention or interaction with the living individuals for research purposes; or (ii) obtain individually identifiable private information about the subjects for research purposes; or (iii) obtain the informed consent of human subjects for research.

e. Engagement in Research Not Involving Human Subjects: An institution is not engaged in human subjects research if its investigators are not obtaining either data through intervention or interaction with living individuals, or identifiable private information.

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

g. Institutional Review Board (IRB): A committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects (see Army Regulation 70-25, Appendix C-1). Selection for the board is in accordance with Federal guidelines outlined in 21 CFR 56.107 and 32 CFR 219.

h. Institutional Review Board (IRB) Staff: Individuals who are employed in direct support of a USAMRMC human research protection program, (i.e., IRB Support Staff, Human Subjects Protection Scientists, IRB Administrators, Human Protection Administrators).

i. Key Study Personnel: Persons who will be involved in the design or conduct of the human subjects research and will have direct contact with subjects or their identifiable records/data and /or specimens (e.g., Principal Investigator, Co-Investigators, Associate and Sub-Investigators, Key Support Staff and Coordinators).

j. Ombudsman: An individual not associated with the human subjects research protocol, appointed to be available to serve as an observer and reporter of any coercion when conducting recruitment group briefings with active duty personnel, and to ensure that subjects understand that participation is voluntary (see DoD Directive 3216.02). The ombudsman requirement may also be implemented at the discretion of the WRAIR IRB.

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k. Research Involving Human Subjects: Any research that involves human subjects, identifiable human data, or identifiable human anatomical substances (Defined in the WRAIR Policy Letter #11-50).

l. Research Manager: Individuals involved in the management of research involving human subjects (e.g., Research Area Directors, Program and/or Project Managers, Grants Managers, Grants Officer's Representatives, and Contract Officer Representatives).

m. Research Support Personnel: Persons involved in the research with no direct contact with subjects or identifiable data/specimens (e.g., Laboratory Technicians, Project Scientists).

n. Staff Log: A list describing the roles and responsibilities of research support personnel with regard to their research support activities.

o. Training File: A file that consists of human subjects (and other research skill related) training completion certificates for all personnel involved in a research protocol.

5. BACKGROUND:

a. To comply with Federal, DOD, Army, and USAMRMC regulatory requirements, WRAIR personnel who directly support human subjects research must complete with a passing score initial and continuing human research protection education and training.

b. The 32 CFR 219.107 directs that IRBs must have an understanding of "applicable law, and standard of professional conduct and practice."

c. DOD Directive 3216.02, Protection of Human Subjects, requires:

(1) Awareness of human subjects protection requirements be established for all DOD personnel involved in the conduct, review, or approval of research involving human subjects;

(2) Activities will be commensurate with the duties and responsibilities of the participants in the process of protection of human subjects of research and compatible with Department of Health and Human Services' Office of Human Research Protections policies; and

(3) Research ethics training will be incorporated into the continuing education program at all DOD Component activities that conduct research involving human subjects.

d. Message, ALARACT 031/2008, Army Human Subjects Protection Requirements, requires that all Army institutions which conduct, sponsor, fund, or otherwise support

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human research must have a written plan that includes the institution's human subjects protection continuing education and training program.

6. APPLICABILITY AND SCOPE:

a. This policy applies to WRAIR personnel who are involved in human subjects research as Institutional Officials, Directors, Department Chiefs, Research Managers, IRB members and staff, investigators, key study personnel, research support personnel, ombudsmen, and research monitors.

b. This policy is also applicable to WRAIR personnel who are conducting research determined not to involve human subjects, contractors who conduct human subjects research under the WRAIR Human Research Protection Plan, and collaborating non-WRAIR personnel where no alternate institutional training policy or program exists.

Note: For research sponsored by the DOD, non-WRAIR researchers must provide proof of their institutions' human subjects protection training requirements and written confirmation that they have met their institutions' requirements. If no alternate institutional training program exists, this policy must be followed as the default requirement for non-WRAIR researchers.

7. POLICY:

a. WRAIR and its detachments that conduct, review, approve, support, manage, or oversee human subjects research must ensure that their personnel demonstrate and maintain sufficient knowledge of the ethical principles and regulatory requirements for protecting research participants.

b. Research personnel must complete initial and ongoing education and training in the protection of human subjects in research at a level commensurate with their roles and responsibilities in human subject research (Enclosure 1).

8. IMPLEMENTATION:

a. Human Subject Protection Training Options:

(1) University of Miami Collaborative Institutional Training Initiative (CITI): Effective 3 October 2008, the preferred human subjects training program for the WRAIR. This is a web-based, self-contained course oriented to both biomedical and social behavioral research. CITI also offers a number of training modules in several foreign languages through its international sites. Use of CITI brings WRAIR in step with USAMRMC policy #2010-33, all Army Military Treatment Facilities (MTFs), and the Navy HRPP.

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(a) Training will be specific to the functions of the researcher or management staff.

(b) The following options will be available on the WRAIR CITI website:

- 1) Investigator/key study personnel with the research concentration in:
 - a) Biomedical research
 - b) Socio-behavioral research
- 2) IRB Members and Staff, Compliance Officer (Quality Activities)
- 3) Supervisor of human subjects research
- 4) Research Support Staff working only with human data or specimens
- 5) Research Monitor
- 6) Ombudsman
- 7) Department Chairs, IPT Managers, and Division Directors
- 8) Institutional Official

(2) For our international collaborations, a specific investigator or program at WRAIR may propose use of existing programs or use of their own institutional program that meets the requirements of this policy. For any such proposal, course content should be equivalent to the breadth and depth of content covered in the CITI course modules. Such training must be acknowledged in writing through the Director, DHSP, WRAIR.

(3) For a consultant, whether they are or are not required to take human subjects training is dependent on their responsibilities listed within the role and responsibilities section of the protocol.

b. Initial Human Subject Protection Policy:

(1) Initial training must be completed before assumption of human subjects research duties.

(2) If a protocol qualifies for approval as exempt research in accordance with 32 CFR 219.101(b), [research involving the collection of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded in such a way that subjects cannot be identified directly or indirectly], then the CITI Training requirements for WRAIR staff are to complete modules 1-4 of the CITI Biomedical Courses. This will provide the minimum awareness of human subjects protection education required by the DOD Directive 3216.02, Protection of Human Subjects.

(3) WRAIR Research Personnel working with data and/or specimens, where 32 CRF 219 does not apply to research activities, (per the WRAIR Policy Letter #11-50,

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and which has been determined by the Chair of the WRAIR IRB or Director, DHSP, WRAIR, as not to involve human subjects research) are required to complete modules 1-4 of the CITI Biomedical Courses. This training will provide the minimum awareness of human subjects protection education required by the DOD Directive 3216.02, Protection of Human Subjects.

(4) Additionally, this memo serves to clarify that WRAIR personnel participating on projects that are determined to not involve research (in accordance with WRAIR Policy Letter #11-50), by the WRAIR Institutional Review Board (IRB) Chair or Director, Division of Human Subjects Protection (DHSP), do not need to take or provide human subjects protection training.

(5) Note: Individuals **must** receive a minimum score of 80% on each module quiz to receive credit for completed modules.

c. Continuing HSP training:

(1) Frequency: Research personnel must provide documentation of completion and a passing score of human subjects protection training completed every three years. The only exceptions are ombudsmen and consultants. (see Enclosure 1). WRAIR DHSP staff will review the training file for the PI during the annual continuing review.

(2) Content: Research personnel are allowed to complete the refresher modules for the CITI program or an alternate course. However, only training offerings directly relevant to human subjects protections will meet USAMRMC criteria for continuing training. Please refer to the Enclosure 2 for current approved continuing HSP training requirements.

d. Training Documentation:

(1) Individual Responsibility: Individual personnel are responsible for keeping accurate records of his/her initial and continuing training. PIs and key study personnel, and research monitors must provide verification and/or copies of training records when submitting research protocols.

(2) PI Responsibility: The PI must maintain records of documentation of HSP training for each research team member. The PI must maintain a staff log and training files. A training file must be kept for each research team member, including those who do not have direct contact with human subjects but who work with human data or specimens from exempt or research not involving human subjects (NHSR). The PI must also keep a training file for each researcher or study staff (etc.), who is not explicitly listed on the protocol but who is serving as laboratory support. (Training recommended: Group #4 "Biomedical Research Support Personnel" or Group #10 "Social Behavioral Research (SBR) Research Support Personnel")

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(3) Institutional Responsibility: Institutions are responsible for verifying and storing training documents (electronic and/or paper copy). Institutions should verify whether investigators, key study personnel, and research support staff have met training requirements prior to the Commander's approval authorization for research protocols or a determination by the WRAIR DHSP that a study is NHSR. WRAIR DHSP maintains the institution's CITI license and the central electronic documentation for all personnel using the WRAIR CITI program.

e. Other Training:

(1) Health Insurance Portability and Accountability Act (HIPAA) training is not a human subjects research training initiative. Research staff must follow the USAMRMC's training requirement for HIPAA compliance. The IRB reserves the right to require research staff to take HIPAA modules as a part of CITI.

(2) Good Clinical Practices (GCP) certification for Investigational New Drug (IND) studies is the responsibility of the Sponsor. Research staff must follow the study Sponsor's requirements for GCP compliance. The IRB reserves the right to require research staff to take GCP modules.

9. The Point of Contact for this policy is the Director, Human Subjects Protection Branch, at (301) 319-9940 or wrairdhsp@amedd.army.mil.

Signature is on file

RALPH L. ERICKSON
COL, MC
Commanding

DISTRIBUTION:
A&B

Encls:
Research Roles
CITI Modules

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Enclosure 1: Research Roles

WRAIR Human Research Protection Program

Collaborative Institutional Review Board Training Initiative (CITI)

If institutions choose CITI for initial and continuing training, see below for requirements. After registering, individuals select the appropriate “Research Role” and “Focus” of modules – Biomedical or Social-Behavioral Research (SBR). See CITI at www.citiprogram.org

Note: Individuals must receive a score of 80% on each module quiz for that module to count toward completed training requirements.

Research Role	Initial Training *	Continuing Training **
<ul style="list-style-type: none"> • Institutional Officials CITI Group 5	Modules 1-3 of CITI Biomedical Courses	3 CITI Modules every 3 years
<ul style="list-style-type: none"> • Department Chairs • IPT Managers • Division Directors CITI Group 2 (Biomedical) or Group 9 (SBR)	Modules 1-9 of CITI Biomedical Courses or Modules 1-8 of CITI Behavioral Courses	6 CITI Modules every 3 years
<ul style="list-style-type: none"> • Investigators (PIs, Co-I, AIs) • Key Study Personnel • Research Monitors CITI Group 3 (Biomedical) or Group 8 (SBR)	Modules 1-19 of CITI Biomedical Courses or Modules 1-14 of CITI Behavioral Courses	6 CITI Modules every 3 years.
<ul style="list-style-type: none"> • Research Support Personnel who work with non-identifiable human data or specimens Exempt Research or Research Determined Not Involving Human Subjects (i.e. NHSR)	Modules 1-4 of CITI Biomedical Courses or Modules 1-4 of CITI Behavioral Courses	3 CITI Modules every 3 years

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(no contact with subjects and/or working coded (unlinked) or anonymized data) CITI Group 4 (Biomedical) or Group 10 (SBR) Enclosure 1: Research Roles (Continued)		
Research Role	Initial Training *	Continuing Training **
<ul style="list-style-type: none"> • IRB Chairs • IRB Members • IRB Staff, HRPP Staff • Compliance Officer CITI Group 1 (Biomedical) or Group 7 (SBR)	Modules 1-21 of CITI Biomedical Courses or Modules 1-16 of CITI Behavioral Courses	6 CITI Modules every 3 years
<ul style="list-style-type: none"> • Ombudsman CITI Group 6	Modules 1, 3, 4, 5, 9, and 17 of CITI Biomedical Course	N/A
<ul style="list-style-type: none"> • Consultant 	N/A	N/A

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Enclosure 2: CITI Modules

* Initial Training

BIOMEDICAL FOCUS

1. History & Ethical Principles
2. Defining Research with Humans - SBR
3. Basic IRB Regulations & Review Process
4. Privacy & Confidentiality – SBR
5. Informed Consent
6. Assessing Risk – SBR
7. Records-based Research
8. Genetic Research
9. Research with Protected Populations
10. Group Harms
11. Internet Research – SBR
12. Research with Prisoners – SBR
13. Research Involving Pregnant Women
14. Research Involving Minors
15. Research Involving Children- SBR
16. SBR for Biomedical Researchers
17. Workers as Research Subjects
18. FDA-regulated research
19. Conflicts of Interest
20. IRB Member
21. Hot Topics – No quiz

SOCIAL-BEHAVIORAL FOCUS

1. History & Ethical Principles – SBR
2. Defining Research with Human Subjects – SBR
3. The Regulations and SBR
4. Privacy and Confidentiality – SBR
5. Informed Consent - SBR
6. Assessing Risks – SBR
7. Records-based Research
8. Research with Protected Populations – Overview
9. Group Harms - Research with culturally or medically vulnerable groups
10. Internet Research – SBR
11. Research with Prisoners – SBR
12. Research with Pregnant Women
13. Research with Children - SBR
14. Conflicts of Interest
15. IRB Member
16. Hot Topics – No Quiz

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Enclosure 2: CITI Modules (Continued)

** Continuing Training

Individuals may choose continuing training from among the following options (this list is not meant to be all encompassing):

1. CITI Continuing Training Modules. (Preferred). Note that some modules do not have a quiz. While, these “no quiz” modules may be used for gaining more knowledge, the refresher certificate submitted should contain modules that have a quiz. CITI Groups 21 (3 module requirement) and 22 (6 module requirement) are designated for the initial refresher training. Modules for subsequent refresher training can be selected from the CITI optional modules in the appropriate group.

2. Programs that meet USAMRMC continuing training requirements sponsored by these, and other, organizations and agencies and provide credit hours toward continuing education:

USAMRMC ORP

Department of Defense, U.S. Navy and U.S. Air Force
Public Responsibility in Medicine and Research (PRIM&R)
Applied Research Ethics National Association (ARENA)
Society of Research Administrators (SRA) International
Office of Research Integrity (ORI)
Office of Human Research Protections (OHRP)
Food and Drug Administration (FDA)
Other institutions' programs

3. The Public Responsibility in Medicine and Research (PRIM&R) Conference, Association for the Accreditation of Human Research Protection Programs (AAHRPP)-sponsored events, and Kennedy Institute, among others, sponsor courses, ethics symposia, and seminars that meet the continuing training requirement.

4. Several professional journals provide home-study programs.

5. Book: *Protecting Study Volunteers in Research*, 2nd Edition, Cynthia McGuire-Dunn, MD and Gary Chadwick, PharmD., MPH, CIP, © October 1, 2002 Continuing education credits for health-care professionals are available.

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