DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
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8 Feb 2021

FCMR-UWZ (1oo)

MEMORANDUM FOR All Personnel, Walter Reed Army Institute of Research (WRAIR)

SUBJECT: WRAIR Policy #26, Initial and Continuing Human Subjects Protection Education and Training Requirements

1. References.

a. Department of Defense Instruction (DODI) 3216.02 (Protection of Human Subjects and Adherence to Ethical Standards in DOD-Conducted and -Supported Research), 15 April 2020.

b. National Defense, 32 Code of Federal Regulations (C.F.R.) §§ 219.101-219.124, (2018).

c. Public Welfare, 45 C.F.R. §§ 46.101-46.505, Revised Common Rule, (2018).

d. Food and Drugs, 21 C.F.R. §§ 50.1-50.56 and §§ 56.101-56.124, (2018).

e. Army Regulation (AR) 70-25 (Use of Volunteers as Subjects of Research).

f. Message, ALARACT 031/2008 (Army Human Research Subject Protection Requirements), 14 February 2008.

g. US Army Medical Research and Development Command (USAMRDC) Policy 12 (Requirements for Initial and Ongoing Education and Training in the Protection of Human Subjects in Research).

h. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Biomedical and Behavioral Research), 1979.

i. WRAIR Policy #24 (Submission of Protocols Involving Human Subjects, Human Information or Biospecimens, for Scientific and Ethical Review).

j. WRAIR Policy #25 (Determination that an Activity is Research Involving Human Subjects).

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*This supersedes WRAIR Policy Letter 11-49, dtd 21 October 2011.

k. U.S. Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP) (Guidance on Engagement of Institutions in Human Subjects Research), 16 November 2018.

l. Memorandum, Office of the Assistant Secretary of Defense (Minimum Education Requirements for DOD Personnel Involved in Human Research Protection), 16 August 2012.

2. History. This policy is being issued in accordance with WRAIR and USAMRDC requirements and is effective upon signature by the WRAIR Commander. This version of the policy will remain in effect until amended or rescinded.

3. Purpose.

a. This policy establishes the minimum requirements for initial and ongoing (continuing) human research protection (HRP) education and training for 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).

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

4. Definitions.

a. Advisors to the Institutional Official (IO): Personnel (e.g., attorneys, ethicists) outside of the Institutional Review Board (IRB) and IRB Office who provide an interpretation of part 219 of title 32, Code of Federal Regulations, DoDI 3216.02, and other HRPP policies to the IO.

b. Data and Safety Monitoring Board (DSMB): A committee of experts, independent of the trial investigators, pharmaceutical sponsor (if any), and funding agency, that periodically reviews the conduct and results of the trial to ensure the safety of participants and the validity and integrity of the data.

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. Research monitors must be independent of the investigative team and possess sufficient educational and professional experience to serve as the subject/patient advocate. Research monitors may be identified by an investigator or appointed by an Institutional Review Board (IRB) or Institutional Official (IO). Responsibilities of Research Monitors are outlined in DODI 3216.02.

d. Human Research Protection Program (HRPP): An integrated institution-wide program coordinated by the Human Subjects Protection Branch (HSPB) with the main purpose of ensuring 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, Human Protections Administrator (HPA), research review groups (the Office of Research Technology and Applications (ORTA), Scientific Review Committee (SRC), Institutional Biosafety Committee (IBC), WRAIR Safety Office, USAMRDC Human Research Protections Office (HRPO), and Translational Medicine Branch), assurances, regulations, policies, standard operating procedures (SOPs), investigators, sponsors, overseas Directors, USAMRDC headquarters, etc.

e. HRPP Support Staff: Individuals who are employed or designated to provide direct support to an institution's HRPP (e.g., Human Protection Administrator, Human Subjects Protection Scientists, and Exempt Determination Officials).

f. Human Subjects Protection Branch (HSPB): The administrative support team for the WRAIR IRB and the WRAIR HRPP (i.e., IRB Support Staff, Human Subjects Protection Scientists, IRB Coordinators, IRB Administrators, Human Protection Administrators, Exempt Determination Officials).

g. Institutional Official (IO): Individual ultimately responsible for implementation of the U.S. Health and Human Services (HHS) Federal Wide Assurance and DOD Assurance of Compliance for the Protection of Human Research Subjects and the associated Human Research Protection Program (HRPP) at an institution engaged in research involving human subjects. Within the USAMRDC, the Commander of the institution/organization engaged in research is the IO.

h. Institutional Review Board (IRB): A committee that has been formally designated to review, approve, and monitor 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, 32 CFR 219, and 45 CFR 46.

i. Investigators: Personnel who are responsible for creating the research protocol and/or conducting the research. There may be more than one investigator on a protocol. Investigators may be principal, associate, laboratory, sub- or co-investigators (Note: the terms associate, sub-investigator or co-investigator are often used interchangeably).

j. Minimum Education Requirements Framework (MERF): A framework for educational training requirements for DoD personnel in key roles of a DOD HRPP.

k. Ombudsperson: An individual that shall not be associated in any way to the research and shall be present during the recruitment in order to monitor that the voluntary involvement or recruitment of the Service members is clearly and adequately stressed and that the information provided about the research is clear, adequate, and accurate. The ombudsperson may also serve as research monitor. The decision to require the appointment of an ombudsperson should be based, in part, on the human subject population, the consent process, and the recruitment strategy (see DOD Instruction 3216.02). The Ombudsperson requirement may also be implemented at the discretion of the WRAIR IRB.

l. Research Administrators: Personnel responsible for the management or administrative oversight of research involving human subjects (e.g. Program Area Directors; Program and/or Project Managers; Grants Managers; Grant Officer's Representatives; Science Officers; and Contract Officer Representatives).

m. Research Coordinators, Clinical Coordinators, and Study Coordinators: Personnel responsible for conducting research under the auspices of an investigator, or personnel involved in the preparation and administration of research protocols. In addition to investigators, these individuals are often referred to as “key personnel”.

n. 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, Contract Officer Representatives, etc.).

o. Research (Human) Subjects: A living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

p. Research Support Personnel: Personnel who are engaged in conduct of the research, but who are participating in a limited or defined part of the protocol under the direct supervision or guidance of an investigator (e.g. consultants, data entry staff, data analysts, laboratory personnel, recruiters, etc.).

q. Staff Delegation Log: A list of staff for a specific protocol describing the individual roles and responsibilities of research support personnel with regard to their research support activities; it may also include training on each version of the protocol and when their study participation begins and ends.

r. Subject Advocates: Personnel who are not part of the research team and who have been appointed by the IRB or are identified in the IRB-approved protocol to act on behalf of the research subject.

s. Training File: A file that consists of signed and dated Curricula Vitae (CVs) and human subjects protection (and other related research skill) training certificates for all personnel involved in a human subjects research protocol.

5. Background.

a. WRAIR is committed to upholding the highest standards of research conduct, including the ethical treatment and protection of human subjects in research. Effective research protections require understanding and knowledge of ethical research principles, regulations, guidelines, policies and procedures that govern the conduct, monitoring and support of human subjects research activities.

b. To comply with Federal, DOD, Army, and USAMRDC regulatory requirements, WRAIR personnel who directly support human subjects research must complete the required human subjects research protection education and training (initial and continuing).

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

d. DODI 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research, 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' OHRP 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.

e. ALARACT 031/2008, Army Human Research Subject Protection Requirements, requires that all Army institutions which conduct, sponsor, fund, or otherwise support human research must have a written plan that includes the institution’s human subjects protection continuing education and training program.

f. Office of the Assistant Secretary of Defense memorandum, Minimum Education Requirements for DOD Personnel Involved in Human Research Protection, identifies the minimum education requirements framework for DOD personnel involved in human subject research.

g. USAMRDC Policy establishes baseline requirements for the initial and ongoing education and training in the protection of human subjects.

6. Applicability and Scope.

a. This policy applies to WRAIR personnel who are involved in human subjects research as IOs, Directors, Department Chiefs, Research Managers, IRB members and staff, Investigators, Protocol Chairs, Research Coordinators, Research Administrators, Research Support Personnel, Ombudspersons, and Research Monitors.

b. This policy is applicable to WRAIR personnel who are conducting exempt research, research determined not to involve human subjects (also referred to as "research not involving human subjects" or "NHSR"), and contractors who conduct human subjects research under the WRAIR HRPP.

c. This policy is also applicable to non-WRAIR personnel affiliated with an institution where no alternate human subjects protection training requirements policy or program exists.

Note: For research sponsored or supported by the DOD, collaborating non-WRAIR personnel (investigators, research monitors, ombudspersons, as applicable) must provide documentation 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 collaborating non-WRAIR personnel.

7. Policy.

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

b. WRAIR 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 as outlined in this policy (Enclosure 1). For personnel with more than one role in human subjects research, the modules associated with the role with the greater responsibility should be completed.

8. Execution.

a. Human Research Protection Training Options:

(1) University of Miami Collaborative Institutional Training Initiative (CITI): CITI is 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. Completion of the CITI modules outlined in Enclosure 1 satisfies the minimum initial and ongoing education and training requirements in the protection of human subjects for WRAIR personnel involved in human subjects research.

(2) For international collaborations, a specific investigator or program may propose use of existing programs or use of their own institutional program that meets the requirements of this policy. Such training must be acknowledged in writing through the Director, HSPB, WRAIR (or designee), and must meet the following requirements:

(a) Course content must be determined to be equivalent to the breadth and depth of content covered in the CITI course modules and required by reference.

(b) Initial training programs must evaluate participants' knowledge, learning, or meeting of the training program objectives, e.g. through a quiz. Successful completion of initial and refresher training requirements must be documented.

(c) Course content must be appropriate to individuals' level of involvement in human subjects research, type of research (e.g. research involving vulnerable populations) and to their duties and responsibilities.

(d) Program content, learning objectives, speaker qualifications, attendance, date completed, etc., must be clearly documented.

b. Initial Human Research Protection Training: WRAIR personnel will complete role-based required human research protection training and educational topics before assuming their HRPP duties. For personnel with more than one role in human subjects research, the modules associated with the role with the greater responsibility should be completed. Personnel may assume their duty position, but may not be involved in any human subjects research or HRPP actions until the required human research protections training is complete.

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

c. Continuing Human Research Protection Training:

(1) As required by reference *m*, WRAIR personnel will repeat role-based required human subjects research protection training at least every three years, beginning from the date of initial training completion.

(2) As required by reference *m* and due to constantly evolving ethical and regulatory issues, WRAIR personnel must also participate in continuing human subjects protection education during the intervening years. To comply with this requirement, WRAIR personnel may complete either refresher modules for the CITI program or an alternate course. Only training offerings directly relevant to human subjects research protections will meet the criteria for continuing training. Refer to the Enclosure 2 for current approved continuing human research protection training requirements.

d. Training Documentation:

(1) Individual Responsibility: WRAIR personnel will maintain accurate and up to date documentation of the completion of initial, follow up, and continuing human research protection training. As required by reference *k*, the documentation supporting award of the certificate must be descriptive (e.g., course content, hours of training). Refer to Enclosure 3 for a sample training certificate. Verification and/or copies of human research protection training records for all study team members must be included as part of a protocol submission packet.

(2) Principal Investigator (PI) Responsibility: The PI must maintain a current staff delegation log and human research protection training files. Human research protection training files 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 biospecimens. The PI must also verify and document that research study support staff not explicitly listed on the protocol (e.g. laboratory support staff) have completed and are up to date with their role-based required human research protection training. These records must be accessible for at least three years after the completion of non-exempt human subjects research studies.

(3) Institutional Responsibility: Institutions are responsible for verifying and storing human research protection training documents (electronic and/or paper copy). Institutions should verify whether investigators, research coordinators, research administrators, research support staff, and research monitors have met human research protection training requirements prior to the issuance of the Commander's approval authorization or of the determination by the WRAIR HSPB. WRAIR HSPB maintains the Institute's CITI subscription and the central electronic access for all personnel using the WRAIR CITI program. WRAIR HSPB also maintains relevant training documentation for IRB members and support staff.

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 USAMRDC's training requirement for HIPAA compliance. The WRAIR IRB reserves the right to require research staff to take HIPAA modules as a part of CITI training.

(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 WRAIR IRB reserves the right to require research staff to complete GCP training.

9. Point of contact for this memorandum is [redacted]

Signature on file

3 Encls
1. Training Requirements
2. Continuing Education Options
3. Alternate Training Certificate

Enclosure 1: Human Subjects Protection Education and Training Requirements

Minimum requirements for initial and ongoing education and training in the protection of human subjects in research using the University of Miami CITI online education program and other DoD-specific content.

Note 1: Individuals must receive a score of 80% or more on each module quiz for that module to count toward completed training requirements.

Note 2: The CITI Groups listed in the table below are part of WRAIR's CITI curriculum.

Research Role	Role-Based Training	Continuing Training* (Intervening Years)
Institutional Officials (IOs) (HRPP Role Category 1)	CITI Group 5 or equivalent content; IO Training with Institutional Human Protection Administrator (HPA). Repeat every 3 years.	CITI refresher (Group 21) or IO training with HPA at least once during intervening years - consisting of a minimum of 3 unique modules
Research Administrators (HRPP Role Category 2)	CITI Group 2 or equivalent content. Repeat every 3 years.	CITI refresher (Group 21) training at least once during intervening years - consisting of a minimum of 3 unique modules
IRB Chairs, IRB Members and Support Staff; HRPP Support Staff; Compliance Officer (HRPP Role Category 3)	CITI Group 1 or equivalent content. Repeat every 3 years.	CITI refresher (Group 22) training at least once during intervening years - consisting of a minimum of 6 unique modules with quiz
Ethical and Legal Advisors to IOs, IRBs, or HRPPs (HRPP Role Category 4)	CITI Group 4 or equivalent content. Repeat every 3 years.	CITI refresher (Group 21) training at least once during intervening years - consisting of a minimum of 3 unique modules

Investigators (HRPP Role Category 5)	CITI Group 3 or equivalent content. Repeat every 3 years.	CITI refresher (Group 22) training at least once during intervening years - consisting of a minimum of 6 unique modules with quiz
Research/Clinical/Study Coordinators (HRPP Role Category 8)	CITI Group 3 or equivalent content. Repeat every 3 years.	CITI refresher (Group 22) training at least once during intervening years - consisting of a minimum of 6 unique modules with quiz
Research Support Personnel** (HRPP Role Category 6) **Note: If research support personnel are interacting with subjects and/or have access identifiable private information or identifiable biospecimens, training corresponding to HRPP Role Category 8 (see above) must be completed.	CITI Group 4 or equivalent content. Repeat every 3 years.	CITI refresher (Group 21) training at least once during intervening years - consisting of a minimum of 3 unique modules with quiz
Research Monitors (HRPP Role Category 7)	CITI Group 3 or equivalent content. Repeat every 3 years.	CITI refresher (Group 22) training at least once during intervening years - consisting of a minimum of 6 unique modules with quiz
Ombudspersons; Subject Advocates (HRPP Role Category 7)	CITI Group 6 or equivalent content. Repeat every 3 years.	CITI refresher (Group 21) training at least once during intervening years - consisting of a minimum of 3 unique modules with quiz

Research Subjects (HRPP Role Category 10)	There is no required training for these individuals. However, training materials will be made available to the subjects of WRAIR-conducted or supported research upon request.	N/A

**Continuing Training - As required by the Office of the Assistant Secretary of Defense Memorandum, Minimum Education Requirements for DoD Personnel Involved in Human Research Protection, WRAIR personnel will repeat the role-based required human subjects research protection training at least every three (3) years. WRAIR personnel must also complete continuing education during the intervening years.*

Enclosure 2: Continuing Education Options

Individuals may choose continuing training from among the following options (this list is not meant to be all encompassing. Please consult with the HSPB if planning to use programs/courses listed below in items 2 -4):

1. CITI Refresher 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 (refer to Enclosure 1). CITI Groups 21 (3 unique module requirement) and 22 (6 unique module requirement) are designated for refresher training. Additional modules can be selected from the CITI optional modules in the appropriate group.

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

USAMRDC ORP
Department of Defense, U.S. Navy and U.S. Air Force
Public Responsibility in Medicine and Research (PRIM&R)
Office of Research Integrity (ORI)
Office of Human Research Protections (OHRP)
Food and Drug Administration (FDA)
Association of Clinical Research Professionals (ACRP)
Society of Clinical Research Associates (SOCRA)
Association for the Accreditation of Human Research Protection Programs (AAHRPP)
Other institutions' programs

3. Sponsor courses, ethics symposia, and seminars that meet the continuing training requirement.

4. Several professional journals provide home-study programs.

Note: Documentation of completing the above listed continuing training options needs to be provided (see Enclosure 3).

Enclosure 3: Alternate Training Certificate Sample

Note: The Alternate Training Certificate is to be filled out by the individual who completed the alternate education requirements for their respective HRPP role/category, and is to be validated by the PI and/or HSPB. The Alternate Training Certificate is to be stored in accordance with the requirements outlined in section 8.d of this policy.

DoD Human Research Protection Program (HRPP)
Summary of Human Subjects Protection Education

[Print name]_____has completed the education requirements for the HRPP role/category(s) indicated below and has completed the education requirements in the special topic(s) indicated below.

Date required training completed:_____This certificate expires on: _____

Individual validating the education record:

Signature: _____ Date:_____

Printed Name: _____

E-mail:_____Phone: _____

Completion of Required Educational Topics in the Following Role(s) (check all that apply)

____ Institutional Officials
____ Investigators
___ Ombudsperson,
Subject Advocates, DSMBs
___ IRB Chairs, IRB Members,
IRB and HRPP Support Staff,
____ Compliance Officer
____ Research Monitors
____ Protocol Chair
___ Advisors to the Institutional Official
_____ Research Managers
_____ Research Support Personnel
_____ Research Coordinators, Clinical Coordinators, Study Coordinators
____Research Administrators
____Research Subjects
____Other (specify):_____

Completion of Ongoing (Continuing) Educational Topics

___ Attendance at Human Research Protection Event:
Event Name: _____
Date Attended: _____
Credit Hours Earned: _____
___ Home-study Program Completed
Program Name:_____
Date Completed: _____