DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
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FCMR-UWZ (1200B) 10 April 2024

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

SUBJECT: WRAIR Policy #26, Initial and Continuing Human Subjects Research 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), 29 June 2022.

b. National Defense, 32 Code of Federal Regulations (CFR) §§ 219.101-219.124, (2018) (referred to as the 'Common Rule').

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

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

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

f. U.S. Army Medical Research and Development Command (USAMRDC) Policy 12 (Requirements for Initial and Ongoing Education and Training in the Protection of Human Research Subjects), 07 December 2022.

g. 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.

h. 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 includes new Collaborative Institutional Training Initiative (CITI) Program online education requirements as outlined in the revised version of the USAMRDC Command Policy 12. This version of the policy is effective immediately and shall remain in effect until rescinded or superseded in writing, or when it exceeds its expiration on 10 April 2026.

3. Purpose.

a. This policy establishes the minimum requirements for initial and ongoing

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*This supersedes WRAIR Policy #26, dated 27 January 2022.

(continuing) human research protection (HRP) education and training for personnel employed by or affiliated with the WRAIR who conduct, review, approve, acknowledge, 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), IRB Office or HRPP staff who provide an interpretation of part 219 of title 32, CFRs, DoDI 3216.02, and other HRPP policies to the IO or designee.

b. Alternate Institutional Official (AIO): Individual delegated to act and sign on behalf of the IO. The AIO must have obtained and maintain the same training as the IO.

c. 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.

d. 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 IRB or IO.

e. Exemption Determination Official (EDO): Individuals who are appointed to perform designated reviews and approvals/acknowledgements.

f. Human Research Protection Official (HRPO): A Federal employee designated by a DoD Component or institution to conduct administrative review and approval of DoD-supported research in accordance with the requirements of the Defense Federal Acquisition Regulation Supplement (DFARS), or comparable requirement, and whose review of DoD-supported research is intended to ensure compliance with DoD human subjects research requirements.

g. 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 Director (HPD), research review groups (Research Programs Office (RPO)Technology Transfer Office (TTO), Scientific Review Committee (SRC), Institutional Biosafety Committee (IBC), WRAIR Joint Safety and Quality Office, and USAMRDC Office of Human and Animal Research Oversight (OHARO), assurances, regulations, policies, standard

operating procedures (SOPs), investigators, sponsors, overseas Directors, USAMRDC headquarters, etc.

h. HRPP Support Staff: Individuals who are employed or designated to provide direct support to an institution's HRPP (e.g., HPD, Human Subjects Protection Scientists (HSPS), IRB Coordinator, EDOs, and Post Approval Compliance Monitoring [PACM] staff).

i. 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, HPDs, EDOs).

j. IO: Individual ultimately responsible for implementation and maintenance of the U.S. Health and Human Services (HHS) Federal Wide Assurance (FWA) and DoD Assurance of Compliance for the Protection of Human Research Subjects and the associated HRPP at an institution engaged in research involving human participants. Within the USAMRDC, the Commander of the institution/organization engaged in research is the IO.

k. 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 participants (see AR 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.

l. 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).

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

n. 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 DoDI 3216.02). The Ombudsperson requirement may also be implemented at the discretion of the WRAIR IRB.

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

p. 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".

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

r. Research (Human) Participants: 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.

s. Research Support Personnel: Personnel who are engaged in the 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.).

t. 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.

u. 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 participant.

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

5. Background.

a. WRAIR is committed to upholding the highest standards of research conduct, including the ethical treatment and protection of human participants 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. 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 participants.

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. Please note that WRAIR personnel includes those individuals located at each of the WRAIR Directorates.

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 participants 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 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. The CITI program regularly updates the course content, as well as offers 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. Requirements are also outlined in Enclosure 1 for research not involving human subjects (i.e., Not Human Subjects Research [NHSR] activities) and Exempt human subjects research. WRAIR maintains a CITI Program subscription that WRAIR and its personnel may access to meet the requirements set forth in this policy.

(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 training and educational topics before assuming their respective human subjects research related 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 *f* 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 *f* and due to constantly evolving ethical and regulatory issues, WRAIR personnel are to participate in continuing human subjects protection education during the intervening years. Only training offerings directly relevant to human subjects research protections will meet the criteria for continuing training. Refer to the Enclosure 1 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. If completing the requirement through the CITI Program, documentation to meet this requirement must include the list of modules completed as well as the evaluation scores (i.e., transcripts). 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 six (6) years after the completion of non-exempt human subjects research studies.

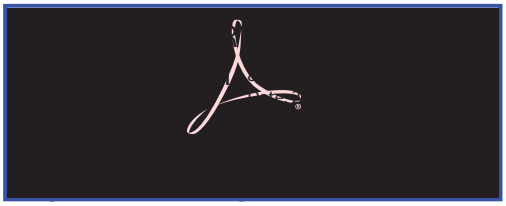
(3) Institutional Responsibility: Institutions are responsible for verifying and storing human research protection training documents (electronic and/or paper copy). Institutions should verify whether investigators, research coordinators, research administrators, research support staff, and DoD research monitors have met human research protection training requirements prior to the issuance of the Commander's approval authorization or 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 the IO, AIO(s), 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 or other 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 Ms. Jody Ference, Director, Human Subjects Protection Branch (FCMR-UWS-HP) at jody.l.ference.civ@health.mil or 301-319-9940.



1 Encl
1. Training Requirements

Enclosure 1: Human Subjects Protection Education and Training Requirements

Minimum requirements for initial and ongoing (continuing) 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	CITI Training	Additional Training
Commanders/Directors/IOs, AIOs	CITI Group 4 or equivalent content. Repeat every 3 years.	IO Training with WRAIR HPD. Continuing education per USAMRDC or subordinate organization.
Advisors to the IO	CITI Group 4 or equivalent content. Repeat every 3 years.	Continuing education per USAMRDC or subordinate organization.
HRPP Support Staff; HPDs; HRPOs; EDOs; IRB Members; Support Staff; PACM Staff	CITI Group 1 (biomedical), **and** 2 (socio-behavioral), **and** 3 (HRPP support) or equivalent content. Repeat every 3 years.	Continuing education per USAMRDC or subordinate organization.
USAMRDC Investigators and Research Support Personnel engaged in human subjects research, interacting with subjects and/or have access to identifiable private information or identifiable biospecimens; Ombudspersons listed on human subjects research protocols	CITI Group 1 for biomedical research **or** CITI Group 2 for social-behavioral-educational research or equivalent content. Repeat every 3 years.	Continuing education per USAMRDC or subordinate organization.
Research Administrators	CITI Group 1 or equivalent content. Repeat every 3 years.	Continuing education per USAMRDC or subordinate organization.
USAMRDC Investigators and Research Support Personnel not engaged in human subjects research (NHSR) (i.e., working strictly with non-identifiable specimens or data) or exempt research **Investigators and Research Support Personnel not engaged in research (NR)	CITI Group 4 Repeat every 3 years.	Continuing education per USAMRDC or subordinate organization.

**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.*

** While Group 4 is not required for those carrying out projects determined to be "Not Research" (Example: Public Health, Quality Assurance), this Group is strongly encouraged for staff to understand when/if a project changes to involve research aspects.

CITI Program Module Topics

Group 1 (Biomedical, Research Administrators) Modules:

1. Belmont Report and Its Principles (ID 1127)
2. History and Ethics of Human Subjects Research (ID 498)
3. Basic Institutional Review Board (IRB) Regulations and Review Process (ID 2)
4. Informed Consent (ID 3)
5. Social and Behavioral Research (SBR) for Biomedical Researchers (ID 4)
6. Records-Based Research (ID 5)
7. Genetic Research in Human Populations (ID 6)
8. Populations in Research Requiring Additional Considerations and/or Protections (ID 16680)
9. Research Involving Prisoners (ID 8)
10. Research Involving Children (ID 9)
11. Avoiding Group Harms – U.S. Research Perspectives (ID 14080)
12. Research Involving Pregnant Women, Fetuses, and Neonates (ID 10)
13. International Studies (ID 971)
14. FDA-Regulated Research (ID 12)
15. Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID 14777)
16. Research and HIPAA Privacy Protections (ID 14)
17. Vulnerable Subjects – Research Involving Workers/Employees (ID 483)
18. Conflicts of Interest in Human Subjects Research (ID 17464)
19. DoD-Unique Requirements (ID 17552)
20. (Optional) Consent and Biobanks and Associated Databases (ID 17254)

Group 2 (Social & Behavioral) Modules:

1. Belmont Report and Its Principles (ID 1127)
2. Conflicts of Interest in Human Subjects Research (ID 17464)
3. DoD-Unique Requirements (ID 17552)
4. History and Ethical Principles – SBE (ID 490)
5. Defining Research with Human Subjects – SBE (ID 491)
6. The Federal Regulations – SBE (ID 502)
7. Basic Institutional Review Board (IRB) Regulations and Review Process (ID 2)
8. Assessing Risk – SBE (ID 503)

9. Informed Consent – SBE (ID 504)
10. Privacy and Confidentiality – SBE (ID 505)
11. Records-Based Research (ID 5)
12. Genetic Research in Human Populations (ID 6)
13. Research with Prisoners – SBE (ID 506)
14. Research with Children – SBE (ID 507)
15. International Research – SBE (ID 509)
16. Internet-Based Research – SBE (ID 510)
17. Research and HIPAA Privacy Protections (ID 14)
18. Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID 14928)
19. Vulnerable Subjects – Research Involving Workers/Employees (ID 483)

Group 3 (HRPP Support) Modules:

1. The IRB Member Module – 'What Every New IRB Member Needs to Know' (ID 816)
2. Consent and Subject Recruitment Challenges: Remuneration (ID 16881)
3. Consent in the 21st Century (ID 17060)
4. Consent and Subject Recruitment Challenges: Therapeutic Misconception (ID 17259)
5. Consent and Cultural Competence (ID 17263)
6. Informed Consent and Incidental Findings in Research with Human Subjects (ID 17342)
7. DoD-Unique Requirements (ID 17552)

Group 4 (Institutional Official and Advisors to the Institutional Official, Individuals engaged in NHSR/NR*) Modules

1. Belmont Report and Its Principles (ID 1127)
2. History and Ethics of Human Subjects Research (ID 498)
3. Conflicts of Interest in Human Subjects Research (ID 17464)
4. DoD-Unique Requirements (ID 17552)
5. Defining Research with Human Subjects – SBE (ID 491)

*While Group 4 is not required for those carrying out projects determined to be "Not Research" (Example: Public Health, Quality Assurance), this Group is strongly encouraged for staff to understand when/if a project changes to involve research aspects.