



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

REPLY TO
ATTENTION OF

FCMR-UWZ (1200B)

10 April 2024

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

SUBJECT: WRAIR Policy #34, Personnel and Family Participation in WRAIR Research Studies

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. Integrated Addendum to ICH E6 (R1) (Guideline for Good Clinical Practice E6 (R2)), Current Step 4 Version, 9 November 2016.
- c. Army Regulation (AR) 70-25 (Use of Volunteers as Subjects of Research).
- d. WRAIR Policy #24 (Submission Requirements for Human Subjects, their Information or Biospecimens).
- e. WRAIR Policy #28 (Compensation and Permission for Participation of Federal Personnel in WRAIR Research Studies).
- f. WRAIR Policy #55 (Research Ethics and Integrity Consultation Service).

2. History. This policy is being issued in accordance with WRAIR and United States Army Medical Research and Development (USAMRDC) requirements and is effective upon signature by the WRAIR Commander. This version of the policy includes minor editorial and administrative changes. This version of the policy is effective immediately and shall remain in effect until rescinded or superseded in writing, or when it exceeds its expiration on 10 April 2026.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. This policy aims to ensure that proper protections and appropriate procedural safeguards are in place for WRAIR personnel and certain family members who consider volunteering to participate in WRAIR research protocols, and to preserve the integrity of WRAIR's research by ensuring that research is as free from bias as possible. The goals of this policy are to identify and manage the potential for undue influence to participate and reluctance to withdraw; loss of privacy and confidentiality of

*This supersedes WRAIR Policy #34, dated 02 November 2022

WRAIR personnel- participants; conflicts of interest and commitment; impacts on scientific validity due to these factors; and disruption in team cohesion and perceived or actual expressions of favoritism.

4. Definitions.

a. Conflict of interest/conflict of commitment: Situations in which financial or other personal situations compromise or have the appearance of compromising an individual's professional judgment in reporting or conducting research, or a participant's honest and objective participation in a research protocol.

b. Co-workers: Personnel who work together as members of a laboratory, branch, department, or other functional group within an organization. For the purposes of this policy, personnel are not necessarily co-workers merely because they both work for WRAIR or for the same Center or Forward Directorate.

c. Manager: WRAIR personnel who oversee the day-to-day work or tasks of contractors or cooperative agreement personnel but do not officially supervise those personnel.

d. Study team: Individuals who are responsible for the conduct of a research study, including all of those who are named in the study protocol and/or in the delegation of authority log.

e. Subordinate: WRAIR personnel who are supervised or managed by other personnel.

f. Supervisor (including Team Lead/Contracting Officer's Representative): WRAIR personnel with authority and responsibility to carry out one or more of the following: assign work; allocate resources; hire, fire, evaluate, promote and/or recommend pay raises for other personnel.

g. WRAIR personnel: All U.S. Military and Civilian employees, Foreign Service Nationals/Locally Employed Staff, contractors, cooperative agreement employees, guest researchers, special government employees, volunteers, fellows, students and trainees of WRAIR and its Forward Directorates.

5. Background. WRAIR personnel who participate in WRAIR research protocols contribute to science and may gain important knowledge themselves. Many personnel choose to participate in research that carries no prospect of benefit to themselves because they value participation in research as a kind of altruism or service to science and the general public. Personnel may also be motivated by their interest in the research or by the prospect of receiving financial compensation. When WRAIR

personnel (or certain family members) enroll in WRAIR studies, researchers must identify and manage potential concerns, including protection of the participants' rights and interests, real or perceived conflicts of interest and threats to scientific integrity. These concerns, described below, are amplified when subordinates of the study team enroll in the research study.

a. **Perceived or Actual Undue Influence:** Subordinate personnel in the supervisory chain of the Principal Investigator (PI), Associate Investigator (AI) or program manager/protocol chair might reasonably believe that they are unable to decline or withdraw from participation without professional consequences, including restricted access to resources, poor performance reviews or denial of promotion opportunities. In addition, personnel might construe participation as a way to receive certain benefits, including higher performance ratings, being viewed as a 'team player' or receiving special treatment or priority over other team members with respect to leave or hours. While personnel-participants can sign a statement indicating that they were not coerced into enrolling, often undue influence is subtle and unspoken and is perceived by other team members as well.

b. **Privacy and Confidentiality:** While personnel are generally provided with strong privacy and confidentiality protections of their health information in the context of the workplace, these protections cannot always be guaranteed for personnel who participate in research. In many studies, sensitive data are collected about participants, such as substance use, medical history, illegal activities, and other behavioral information. Even when no sensitive data are collected, the risk for incidental findings exists and presents concerns for personnel. For example, if a pregnancy screening is required, a participant (and members of the study team) might discover an unanticipated pregnancy, affecting their privacy related to her reproductive health decisions.

c. **Conflicts of Interest:** Both investigators and their subordinate personnel who participate in research projects can have conflicts of interest and commitment. For example, personnel might want to dedicate more time to research participation than their professional responsibilities, and supervisors or managers might support this preference, which could negatively affect co-workers and unit effectiveness. Subordinate personnel participating in studies also might be reluctant to report or disclose problems that could negatively affect the study. Such conflicts, even when acknowledged, can result in conscious or unconscious bias that can influence research processes favorably or unfavorably.

d. **Scientific Integrity and Validity of Data:** A major concern resulting from the ethical considerations above is the effect they have on validity of data and integrity of research. Undue influence to participate or refrain from withdrawing can lead to numerous biases, including social-desirability response bias, yielding inaccurate results. Failure to

disclose information honestly could also put participants at risk for various harms, including potential drug-drug interactions or reduced attention to adverse events. The lack of privacy and confidentiality might lead a study participant to withhold information needed for study conduct.

e. Work Unit and Team Cohesion: Because study personnel often function in teams, inequitable opportunity to participate in supervisor/manager-conducted research can lead to numerous team conflicts, such as perceived or actual favoritism, mistrust among colleagues, and inequitable access to supervisor/manager time and attention. Such conflicts might negatively affect the quality of research or workplace cohesion.

6. Applicability and Scope.

a. This policy applies to non-exempt human subjects research protocols (both minimal risk and greater than minimal risk studies) conducted by investigators at WRAIR. Procedures must be implemented before recruiting or enrolling WRAIR personnel or certain family members as participants in such research.

b. This policy does not apply to exempt human subjects research protocols (i.e., protocols determined not to require Institutional Review Board (IRB) review) or to those studies determined to be “not research” or “not research involving human subjects.” This policy also does not apply to non-exempt human subjects research protocols that qualify for expedited IRB review because they involve only:

(1) Prospective collection of biological specimens for research purposes by noninvasive means;

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture; and/or

(3) Survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

c. Notwithstanding the scope as outlined above, any WRAIR personnel who have concerns or questions about being approached for enrollment in exempt studies, specimen collection studies, or other research not covered by this policy may contact the WRAIR HSPB or Research Ethics and Integrity Team for information and assistance. Additional requirements apply to certain categories of WRAIR personnel regarding compensation and supervisor permission for participation in research. See WRAIR Policy #28, Compensation and Permission for Participation of Federal Personnel in WRAIR Research Studies.

7. Policy.

a. WRAIR personnel and their immediate family members generally are permitted to be screened for and enrolled as participants in research studies conducted at or supported by WRAIR. WRAIR personnel may be partially or completely restricted from participating in human subjects research at WRAIR if:

(1) The study protocol specifically prohibits participation of DOD; or WRAIR personnel;

(2) For U.S. Military personnel working at WRAIR, their supervisory chain refuses or does not give permission to participate.

(3) They meet exclusion criteria or other conditions sufficient for denying screening or enrollment that are applicable to non-WRAIR personnel; and/or,

(4) The WRAIR IRB Chair or a member of WRAIR's Research Ethics and Integrity Team has reviewed their case due to ethical concerns and has determined that they should not be allowed to participate in a specific study.

b. Members of the supervisory/management chain for WRAIR personnel may not:

(1) Penalize, sanction, or otherwise adversely affect WRAIR personnel in their work for choosing not to enroll as a participant in human subjects research;

(2) Incentivize, reward, or otherwise favorably affect WRAIR personnel in their work for choosing to enroll as a participant in human subjects research (excluding any compensation approved for all study participants); or

(3) Penalize, sanction, or otherwise adversely affect WRAIR personnel in their work for choosing to withdraw from human subjects research or for reporting problems with a research study to the IRB, Human Subjects Protection Branch (HSPB), the Research Ethics and Integrity Team, their chain of command, or some other appropriate party.

(4) Solicit or recruit their subordinate personnel for participation in a WRAIR research study, either orally or through individual flyers, mail, or email.

(5) Be present during study recruitment activities that include their subordinate personnel or during informed consent processes for subordinate personnel.

c. Members of the supervisory/management chain for WRAIR personnel may share study recruitment materials in a manner that does not target individual subordinate personnel, such as by posting flyers in an area where public announcements are

permitted or sending participation opportunities to large email distribution lists. However, these solicitations should not be sent by supervisors/managers with many subordinate WRAIR personnel (e.g., Center Directors).

d. Investigators of WRAIR research studies that permit enrollment of WRAIR personnel as participants are responsible for:

(1) Ensuring that study practices and procedures meet the requirements of this policy, including requirements for informed consent (Section 7.e);

(2) Maintaining appropriate safeguards to mitigate the ethical and scientific concerns identified in the Background section above; and,

(3) Informing WRAIR personnel who enroll in the research about the requirements of this policy that are relevant to their participation, especially for the classes of participants described in section 7.f.

e. When WRAIR personnel enroll as participants in a research study, the informed consent process must satisfy the following requirements:

(1) Informed consent for WRAIR personnel's participation in a research study may not be obtained by members of their supervisory/management chain. Supervisors/managers are not permitted to be present during the informed consent process for their subordinate personnel. If possible, informed consent for WRAIR personnel's participation should not be obtained by their co-workers.

(2) WRAIR personnel must be informed of any risks to their fitness for duty (e.g., health, availability to perform job, data breach, and deployment readiness of military personnel) and any personal or professional risks related to their status as WRAIR personnel that can result from their participation in the research study.

(3) The Information Sheet on Personnel and Family Participation in WRAIR Research Studies (Appendix A) must be provided to WRAIR personnel who are considering participating in WRAIR research during the informed consent process, if not earlier. If the WRAIR personnel chooses to enroll, they must sign the information sheet and a copy must be included in the study's participant records.

f. To protect participants and scientific validity, special requirements apply to enrolling certain groups as participants in WRAIR research.

(1) The following requirements apply for (i) members of the study team

(personnel named in the study protocol and/or in the delegation of authority log), (ii) subordinate personnel of members of the study team, and (iii) immediate family (spouses, children, siblings, and parents) of the study team:

(a) The IRB Chair or REI consultant must review and approve the PI's request to enroll the participant. Given the issues typically raised by such cases, approval will be granted only in exceptional circumstances.

(b) The participant must be interviewed by a Research Ethics and Integrity Team consultant, or an ombudsperson appointed by the IRB Chair. The interviewer will write a memorandum attesting to the participant's understanding of the special risks and burdens of WRAIR personnel participating in research, including the potential for undue influence, and this report will be included in the study participant's records. The interviewer may require observation of the informed consent process for the participant.

(c) The Research Ethics and Integrity Team consultant or IRB Chair-appointed ombudsperson also will remain available to the participant throughout their involvement in the study to assist with any concerns or questions. The IRB Chair may require the Research Ethics and Integrity Team consultant/ombudsperson to communicate with the participant at a later date to determine if there are any ongoing issues or concerns.

(2) If WRAIR personnel who formally reviewed a protocol (e.g., as a Scientific Review Committee member, HSPB staff, IRB member) wish to enroll as a participant, the IRB Chair or Research Ethics and Integrity Team consultant must review and approve the PI's request to enroll the participant and may require explanation for the request.

g. Per the Department of Defense Instruction (DODI) 3216.02, an ombudsperson must be present when groups of Active-Duty U.S. Military personnel are briefed for recruitment purposes, to ensure that any ensuing participation in research is fully voluntary. For additional requirements specific to Active-Duty personnel, refer to WRAIR Policy #28, Compensation and Permission for Participation of Federal in WRAIR Research Studies.

h. Individuals with questions about the appropriateness of enrolling WRAIR personnel or certain family members as participants in research should consult with the IRB Chair or a member of the Research Ethics Integrity Team, ideally prior to recruitment or screening of WRAIR personnel or certain family members for study participation.

8. Implementation. Unless a research protocol explicitly states that WRAIR personnel and/or certain family members are not permitted to enroll as study participants, the

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protocol must meet the requirements of this policy and must have appropriate safeguards to mitigate the ethical and scientific concerns raised in the Background section above.

9. The points of contact for this policy are Dr. Liza Dawson, IRB chair and Research Ethics and Integrity Team Leader (FCMR-UWS) at Liza.Dawson.civ@health.mil, 301-828-7183, and Ms. Jody Ference, Director, Human Subjects Protection Branch (FCMR-UWS-HP) at Jody.L.Ference.civ@health.mil or 301-319-9940.

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Appendix A: Information Sheet



Appendix A: Information Sheet on Personnel and Family Participation in WRAIR Research Studies

Study Name/Number:

WRAIR personnel (including U.S. Military and Civilian employees, Foreign Service Nationals/Locally Employed Staff, contractors, cooperative agreement personnel, guest researchers, special government employees, volunteers, fellows, students, and trainees of WRAIR or its Directorates) generally are allowed to enroll as participants in research studies conducted at or supported by WRAIR and its Directorates. The purpose of this document is to inform personnel about the special risks and burdens personnel might face when participating in certain types of WRAIR research, and about the protections and resources available for those personnel. This information may apply to family members of WRAIR personnel in some circumstances.

Potential Risks and Burdens

Personnel who volunteer to participate in WRAIR research studies might do so to make altruistic contributions to science and sometimes gain important knowledge themselves. However, personnel who participate in WRAIR research studies might face special risks and burdens, including:

- **Undue Influence:** Supervisors, managers, or co-workers might pressure personnel to participate in research against their better judgment. They might offer or imply that professional rewards will be given for participating in research, or that punishments will be incurred for refusing to participate. Such undue influence is often subtle and unspoken, and even its mere appearance can have a negative effect on the work environment.
- **Breaches of Privacy or Confidentiality:** Some research collects sensitive information about participants, such as substance use, illegal activities, medical history, or other behavioral information. Other research might accidentally discover new information about participants, such as a pregnancy or a genetic illness. This private information about personnel who participate in research might be accessed (intentionally or accidentally) by their supervisors, managers, or co-workers, even when additional protections are put in place.
- **Conflicts of Interest or Commitment:** A research team's interest in enrolling qualified participants might compromise their best judgment about enrolling co-workers or subordinate personnel. Personnel might have personal or professional interests that compromise their ability to participate fully and honestly in research. When not properly managed, such conflicts of interest and commitment can undermine participant safety, scientific quality, and workplace productivity.

Protections and Resources

To address the above concerns about personnel participating in certain types of WRAIR research studies, WRAIR has implemented the following protections and resources:

- Personnel may not be adversely affected for choosing not to participate in WRAIR research or favorably affected for choosing to participate in WRAIR research.
- Supervisors and managers may not be involved in recruiting or consenting their subordinate personnel for participation in WRAIR research.
- Personnel must be informed of any risks to their fitness for duty and any personal/professional risks that can result from participating in WRAIR research.
- Investigators and the WRAIR IRB must ensure that appropriate safeguards are in place to protect the rights and well-being of personnel-participants.
- Some classes of personnel must be interviewed by a member of WRAIR's Research Ethics and Integrity Team or an IRB-appointed ombudsperson before they are permitted to participate in WRAIR research.
- Some classes of personnel must receive specific approval from their supervisor and/or from the IRB Chair before they are permitted to participate in WRAIR research.
- Personnel who are participating or considering participating in WRAIR research may request assistance or advice at any time from the REI team, ombudsperson, IRB Chair, or human research protections staff.

Acknowledgment

Please complete the following:

I am:

- Personnel of WRAIR or its Directorates
Department/office and role:
- Immediate family of a member of the study team
- Other (please specify):

I acknowledge that I have been informed of the potential risks and burdens faced by WRAIR personnel who participate in WRAIR research, as well as the special protections and resources available to me if I choose to participate in WRAIR research.

Signature:

Date:

Printed Name: