



DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
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FCMR-UWZ (100)

27 January 2022

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

SUBJECT: WRAIR Policy #55, Research Ethics and Integrity Consultation Service (REICS)

1. References.

a. Department of Defense Instruction (DODI) No. 3210.7 (Research Integrity and Misconduct), 14 May 2004.

b. Department of Defense Instruction (DODI) No. 3216.02 (Protection of Human Subjects and Adherence to Ethical Standards in DOD-Conducted and -Supported Research), 15 April 2020.

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

d. Office of the Secretary of Defense (Protection of Human Subjects), 32 C.F.R. 219, 1 July 2013.

e. WRAIR Policy #35 (Policy and Procedures for Addressing Allegations of Research Misconduct).

2. History. This version of the policy revises and supersedes the previous version, which was issued 19 March 2021. This version of the policy is effective upon signature and will remain in effect until amended or rescinded.

3. Purpose. This policy aims to support responsible deliberation and decision-making about ethical challenges arising in WRAIR's scientific activities. The WRAIR Research Ethics and Integrity Consultation Service (REICS) assists personnel with identifying, articulating, and navigating bioethical and scientific integrity issues that arise throughout the research process, from project conception and design, throughout the conduct of research, to the communication of findings and consideration of societal implications. The REICS may also be consulted about ethical challenges arising in related areas, such as public health and program evaluation.

4. Definitions.

a. Bioethics: Norms or standards that are essential for protecting individuals' rights

***This supersedes WRAIR Policy #55, dtd 19 March 2021.**

and interests in the areas of medicine, scientific research, public health, social science, the environment, nutrition, human embodiment, sustainability and development, and related areas of concern.

b. Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (32 C.F.R. 219.102 (I)).

c. Research ethics: Norms or standards that are essential for protecting the rights and interests of individuals affected by research, such as animal subjects, human participants, investigators and research staff, and impacted communities. Research ethics norms are sometimes (but not always) codified in laws, regulations, and policies, and their interpretation and application often requires careful judgment and balancing of diverse considerations.

d. Research ethics and integrity consultation: An advisory activity provided by individuals trained in bioethics and integrity in science to assist research teams, regulators, administrators, research participants, or any other person involved in the research enterprise in their navigation of ethics and integrity issues related to planning, conducting, interpreting, or disseminating results of research and research-related activities, as well as recommending practical strategies for managing these issues.¹ Consultation topics vary widely, including, but not limited to, challenges in evaluating potential harms and benefits in animal or human research, conflicts of interest and commitment, scientific best practices, ethical research design, incidental findings, research-related activities, and dual-use research, among other concerns.

e. Research integrity: Norms or standards that are essential for the successful production of scientific knowledge, which is the constitutive aim of research. Some research integrity norms are codified in regulations and policies, but the majority of these standards represent best practices in scientific research and related activities. The interpretation and application of these normative standards often requires careful judgment and balancing of diverse scientific and practical considerations.

f. Research misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results. Research misconduct does not include honest error or differences of opinion.

g. WRAIR personnel: All 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

¹ Adapted from Porter KM, Danis M, Taylor HA, Cho MK, Wilfond BS, Clinical Research Ethics Consultation Collaborative Repository Group. The emergence of clinical research ethics consultation: insights from a national collaborative. *Am J Bioeth.* 2018 Jan 2;18(1):39-45.

of WRAIR and its satellite activities.

5. Background. WRAIR is committed to conducting ethical, relevant, rigorous research. In the course of research, study teams may confront situations in which the best plan of action, ethically or scientifically, is not clear. These questions can present throughout the lifecycle of the research, from hypothesis generation through communicating research findings and assessing their impact. While some of the questions concern what a study team is allowed to do within the relevant regulatory or policy framework (that is, compliance), other questions concern ethics or integrity challenges that are not addressed by laws or regulations, or that result in conflicts or tension among important ethical commitments.

Researchers and program implementers (such as those carrying out program evaluation or public health activities) can benefit from consulting with bioethics and scientific integrity professionals about ethical challenges in their work. Consultation can help researchers identify the ethical dimensions of a project, consider best practices in science, analyze the relevant ethical and scientific issues, find an acceptable path forward, evaluate the decision, and determine course correction when necessary. Proactively addressing concerns about bioethics and scientific best practices supports reflection and deliberation, exercise of judgment, and transparency with regard to decision-making, ultimately enhancing the production of relevant and rigorous science.

While WRAIR research, program evaluation, and public health activities are guided by, and must conform with, regulatory and policy standards (WRAIR policy, DOD, and USG), some issues of ethics and integrity are not explicitly addressed in regulations. In addition, in some cases the best course of action is not straightforward given competing ethical or scientific demands. In these scenarios, falling back on regulatory language and interpretation may not assist researchers in decision-making, and REICS consultation may be desirable.

6. Mission and Scope.

a. Operating under the direction of the Chief of Bioethics, the mission of the REICS is to assist WRAIR personnel with analysis and decision-making about matters of ethics and integrity in science. It provides a group of trained individuals who can help identify ethical and best practice concerns, deliberate about various values and commitments in ethically or practically complex situations, and provide recommendations for a defensible course of action.

b. This policy applies to all WRAIR personnel engaged in research or related activities, whether as investigators, research staff, support staff, or some other role. This includes but is not limited to personnel who conduct research activities of all types (with humans, animals, and/or their samples/data, laboratory science, etc.); those who conduct public health or program evaluation activities; or those whose work supports

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the research enterprise, such as regulatory, business, or quality assurance activities..

7. Policy.

a. Consultation Service. In an effort to facilitate recognition, articulation, and resolution of ethics and integrity issues in all of WRAIR science, the REICS provides a confidential resource for all WRAIR personnel to identify, explore, and resolve issues related to bioethics and scientific integrity. It is helpful to consider potential ethical or scientific challenges early in the research planning process, if possible.

b. Process. The REICS consists of a core group of WRAIR professionals with appropriate training in science and ethics who guide the requester through exploration of the ethical considerations and conflicts that arise in a project or situation, as well as others whose perspectives might benefit from deliberation about the requester's concern. The consultation process consists of identifying and articulating the ethical aspects and possible concerns, providing an analysis of relevant ethical and scientific issues, laying out possible courses of action, and recommending solutions.

c. Recommendations. The recommendations from the REICS are advisory in nature and therefore non-binding. They are intended to identify thoroughly considered options, each with identified risks and benefits, to guide the decisions of WRAIR personnel. Recommendations remain open to revision when new information arises, which might occur after an option is implemented. Although the REICS is not a regulatory or oversight body, its recommendations will consider laws, regulations, and policies that are relevant for the decisions of WRAIR personnel.

d. Availability. Assistance from the REICS is available to:

(1) All WRAIR personnel regardless of role (e.g., investigator, research staff, support staff), affiliation (e.g., Military, Federal civilian, contractor), or location (e.g., WRAIR Forest Glen, AFRIMS, USAMRD-A);

(2) Research personnel from other organizations or institutions working in partnership with WRAIR;

(3) Participants in WRAIR research or their legally authorized representatives;
and

(4) Other individuals or groups as appropriate.

e. Confidentiality. Confidentiality of individuals requesting ethics and integrity consultation and information shared during the consultation process will be protected to the fullest extent possible. Confidentiality cannot be guaranteed in situations that require mandatory reporting, such as formal allegations of scientific

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misconduct, situations in which there is imminent risk of harm to an individual, or issues subject to mandatory disclosure laws.

8. Implementation.

a. All WRAIR personnel will be made aware of the REICS and encouraged to submit a request whenever assistance may be helpful. The telephone number and email address of the Chief of Bioethics will be publicized as one way to initiate a consultation, and any alternative methods for initiating a consultation will also be publicized.

b. Individuals in need of consultation will:

(1) Request REICS assistance by contacting the Chief of Bioethics or designee with a short summary of the situation;

(2) Participate in the consultation and recommend other participants as appropriate;

(3) Determine whether or which of the REICS recommendations to implement; and

(4) Provide the Chief of Bioethics or designee with feedback about the consultation experience.

c. The WRAIR Chief of Bioethics or designee will:

(1) Respond to requests for REICS assistance within two business days or immediately if the situation requires immediate consideration;

(2) Determine whether the request is appropriate for the REICS, and if not, advise the requester of more appropriate channels for assistance;

(3) Solicit assistance from subject matter experts as needed;

(4) Provide a written consultation report including REICS recommendations to the requester within ten business days, unless the developing situation makes this timeline infeasible;

(5) Refer the requester to relevant WRAIR resources as needed;

(6) Request feedback from REICS requesters regarding the consultation experience; and

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(7) Provide the Chief Science Officer, Deputy Commander, and Commander with an annual summary of issues addressed by the REICS.

9. Related Activities.

a. As part of its mission to promote responsible conduct of research at WRAIR, the Chief of Bioethics and designated REICS consultants may offer education, training, and other programs and activities to WRAIR personnel that address topics related to research ethics and scientific integrity.

b. As part of its mission to promote responsible conduct of research more broadly, the Chief of Bioethics and designated REICS consultants may engage in scholarly activities, such as authoring scholarly publications or other information products based on their experiences. Such publications or information products must be compliant with WRAIR publication policy and clearance procedures.

10. Point of contact for this memorandum is [REDACTED], Chief of Bioethics and Research Integrity Officer (FCMR-UWS), at [REDACTED] or [REDACTED].

SIGNATURE ON FILE

CHAD A. KOENIG
COL, SP
Commanding