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-C

JUN 10 2019

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

SUBJECT: Commander's IRB Policy Memorandum #10, Public Health Activity Determination and Oversight Requirements

1. References:

a. Public Welfare, 45 Code of Federal Regulations (C.F.R.) §§ 46.101-46.505, Revised Common Rule (2018).

b. Public Welfare, 45 C.F.R. § 164.512(b), Disclosures for Public Health Activities (2018).

c. Centers for Disease Control and Prevention (CDC), Distinguishing Public Health Research and Public Health Non Research, https://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf.

d. Hodge JG, Gostin LO, "Public Health Practice vs. Research: A Report for Public Health Practitioners Including Cases and Guidance for Making Decisions," Council of State and Territorial Epidemiologists, 24 May 2004.

e. Lee LM, Thacker SB, "Public Health Surveillance and Knowing About Health in the Context of Growing Sources of Health Data. Am J Prev Med. 2011; 41(6): 636-40.

f. Food and Drug Administration. Emergency Use Authorization of Medical Products, http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm.

g. World Health Organization (WHO), Managing Ethical Issues in Infectious Disease Outbreaks, 2016, http://www.who.int/ethics/publications/infectious-disease-outbreaks/en/.

h. World Health Organization (WHO), WHO Guidelines on Ethical Issues in Public Health Surveillance, 2017, http://www.who.int/ethics/publications/public-health-surveillance/en/.

i. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), as codified in "*Standards for Privacy of Individually Identifiable Health Information* (45 C.F.R. §§ 160.101-164.534).

j. Department of Defense Directive (DODD) 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research, 8 November 2011.

k. WRAIR Commander's IRB Policy Memorandum #01, Submission of Protocols Involving Human Subjects, Human Information or Bio-specimens, for Scientific and Ethical Review, 10 June 2019.

l. WRAIR Commander's IRB Policy Memorandum #02, Determination that an Activity is Research Involving Human Subjects, 10 June 2019.

m. WRAIR Commander's Policy Memorandum #13, Biological Select Agent and Toxins (BSAT) Handling and Possession, 10 June 2019.

n. WRAIR Commander's IRB Policy Memorandum #04, Use of Human Cadavers for Research, Development, Test and Evaluation, Education, or Training, 10 June 2019.

2. History: This is the first version of this official policy and is effective upon signature. This version of the policy will remain in effect until amended or rescinded and supersedes any older, existing policies on this topic at WRAIR and its directorates.

3. Purpose: This policy aims to ensure transparency and appropriate oversight of public health support efforts undertaken by the WRAIR and/or its directorates and sets forth the requirements to support the effective and ethical practice of public health activities.

4. Definitions:

a. Emergency Response: A public health activity undertaken in an urgent or emergency situation, usually because of an identified or suspected imminent health threat to the population. The primary purpose of the activity is to document the existence and magnitude of a public health problem in the community and to implement appropriate measures to address the problem.

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

c. Program Evaluation: The systematic application of scientific and statistical procedures for measuring an established program's conceptualization, design, implementation, and utility; making comparisons based on these measurements; and the use of the resulting information to optimize program outcomes and impact.

d. Public Health Activity: One of the four following activities: public health surveillance, program evaluation, outbreak investigation, emergency response.

e. Public Health Authority: An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom is has granted authority, that is responsible for public health matters as part of its official mandate.

f. Public Health Surveillance: The ongoing systematic collection, analysis and interpretation of health-related data with the a priori purpose of preventing or controlling disease or injury, or of identifying unusual events of public health importance, followed by the dissemination and use of information for public health action.

g. Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

5. Background:

a. WRAIR's primary mission is to deliver innovative medical solutions to a range of Force Health Protection & Readiness challenges facing U.S. Service Members now and those anticipated during future operations. With a state of the art laboratory in Maryland, a specialized detachment in Washington, and laboratory and clinical research platforms in Asia, Africa, and Europe, the WRAIR research enterprise provides an extensive array of capabilities and competencies spanning bio-surveillance activities, disease and pathogen characterization, and basic, translational, and clinical research activities. Through this network, our efforts remain relevant and agile to meet the current and future medical countermeasure needs of the U.S. Service Member.

b. Due to WRAIR programs' expertise, occasionally public health entities request WRAIR scientists to assist with non-research activities, such as emergency response or epidemiological consultations (EPICONs), program evaluation, confirmatory testing, public health surveillance, and quality improvement/ quality assurance activities. The OCONUS laboratories perform both infectious disease surveillance and outbreak investigations as part of their core missions. This policy will specifically focus on the requirements when participating in public health activities.

c. While public health activities must be conducted under the authority of public health entities, WRAIR personnel and laboratories can support such activities with expertise, personnel, and resources. When invited or directed to assist, WRAIR personnel are responsible for ensuring the activities they undertake are in compliance with applicable U.S. Federal regulations, DOD/U.S. Army requirements, state and local

laws, and WRAIR policies as well as cognate laws and regulations of foreign governments when this assistance is conducted outside of the United States.

d. Regulatory requirements for research differ from requirements associated with public health practice activities. However, the distinction between public health research, public health surveillance, clinical practice, and public health practice can be difficult to ascertain.

e. Research and non-research determinations require careful consideration by a trained professional or committee. Such determinations are not made by research investigators or program staff. This policy aims to outline that decision making process for public health activities.

6. Applicability and Scope:

a. This policy applies to all WRAIR personnel engaged in public health activities (EPICONS, outbreak investigations, public health surveillance, etc.). This includes WRAIR (and its directorates') military, civilians, and contractors conducting activities with humans and/or their samples/data.

b. Public health activities (research and non-research) conducted at, or supported by WRAIR and its Overseas Directorates, are also subject to the local, state, or national requirements of the host-country, and local institutional policies.

7. Policy: WRAIR has an ethical and legal obligation to ensure that individuals are protected in all activities it conducts. For research activities, the IRB process ensures participant protections. However, WRAIR also conducts numerous public health activities that are considered non-research. These activities include public health surveillance, emergency response, and program evaluation. These non-research activities do not fall under the purview of the IRB, rather they rely on public health best practices and public health ethical guidance to ensure protection of participants.

a. To determine which set of ethical protections applies, the activity must be deemed to be research or non-research. The ultimate decision regarding whether an activity is considered research or non-research lies in the purpose of the project.

b. If the purpose of any part of the project is to develop or contribute to generalizable knowledge, the project is research.

c. If the sole purpose is to prevent or control disease or injury or to improve a public health program, and no research is intended at the present time, the project is non-research.

d. If the purpose changes or data (including specimens) are later used to develop or contribute to generalizable knowledge, then the later project is research and must be submitted and reviewed according to applicable regulations (such as, human subjects protection regulations, animal care and use regulations) before further data collection or analysis.

e. "Generalizable knowledge" is specified in the U.S. human subjects protections regulations (45 C.F.R. 46.101-46.505, also called the Common Rule) as part of the definition of research. The term itself is not defined, but the Office for Human Research Protections (OHRP) has provided guidance that publication of results does not indicate that the project produced generalizable knowledge. OHRP recognizes that non-research activities can produce knowledge, but the intent of a public health activity is to use the data collected (including specimens) to benefit the population or community from which they were collected.

f. All WRAIR public health activities must be reviewed by the Branch/Directorate Director and the WRAIR Human Subjects Protection Branch (HSPB) to determine whether they include research involving human participants. Although general guidance can be provided to assist in classifying public health activities as either research or non-research, no one criterion can be applied universally.

g. It is not unusual for public health activities to involve both research and non-research activities. If public health practice activities include or evolve into research, the research aspects of the project must be submitted to the IRB for consideration.

h. When an activity is classified as research involving human participants, WRAIR will comply with 32 C.F.R. §§ 219.101-219.124, 45 C.F.R. §§ 46.101-46.505 and DODD 3216.02 in assuring human research protections.

i. When an activity is classified as research not involving human participants, WRAIR and its collaborators will comply with WRAIR Institutional Policy.

j. When an activity is classified as public health practice, it should comply with the applicable ethical guidance (for example, WHO Guidelines on Ethical Issues in Public Health Surveillance, Managing Ethical Issues in Infectious Disease Outbreaks).

8. Execution:

a. WRAIR investigators/points of contact (POC) will:

(1) Obtain documentation of the request for public health assistance from the requesting entity.

(2) Complete and obtain signature of the Branch/Directorate Director on the WRAIR Public Health Research / Non-research Determination Form (see Appendix B).

(3) Submit the completed/signed WRAIR Public Health Research/Non-research Determination Form to the HSPB inbox with the request and other applicable reviews.

(4) In extreme situations in which activities must be initiated immediately in order to save life, limb or eyesight, the Investigator/POC may initiate the public health activity. The Investigator/POC must submit a written explanation and justification for engagement through the Branch/Directorate Director to the HSPB Director within 72 hours of initiating the activity along with the completed *WRAIR Public Health Research/Non-research Determination Form.*

(5) Await signed HSPB concurrence memo to begin project/activity.

(6) Monitor the project to determine whether or when the purpose changes from public health activity to generating generalizable knowledge, at which point submission of a human subjects research package must be submitted to HSPB. The package must be submitted to HSPB before the conduct of any activities that constitute research.

(7) Upon completion of the activity, provide a report of the activities (via email or written memorandum) through the WRAIR Branch/Directorate Director to Chief Science Officer, Deputy Commander, and the Director, HSPB.

(8) Maintain a file containing documentation of the submission and approvals of the public health activity.

b. The Branch/Directorate Director will:

(1) Certify that the proposed activity meets the requirements necessary to be considered non-research outlined on the *WRAIR Public Health Research/Non-research Determination Form.*

(2) Have the opportunity to submit a request for appeal within 30 days to WRAIR HSPB in the event of non-concurrence with HSPB determination.

(3) Monitor the project to determine whether or when the purpose changes from public health activity to generating generalizable knowledge, at which point submission of a human subjects research package must be submitted to HSPB. The package must be reviewed and approved by HSPB and/or WRAIR IRB before the conduct of any activities that constitute research.

(4) Ensure Investigator implements activities according to this policy. Failure to comply with this policy can result in disciplinary actions in accordance with Standard Operating Procedure, UWZ-C-606, *and Non-Compliance Procedures.*

(5) Ensure that the WRAIR Investigator/POC submits close-out reports specified above at the conclusion of the investigation.

c. HSPB Director or designee will:

(1) Perform a review by applying CDC policy, Distinguishing Public Health Research and Public Health Non-research, and WRAIR standards in the review of the effort. Additional documents include: WRAIR Commander's IRB Policy Memorandum #01, Submission of Protocols Involving Human Subjects, Human Specimens, and/or Human Data for Scientific and Ethical Review and WRAIR Commander's IRB Policy Memorandum #02, Determination that an Activity is Research Involving Human Subjects, as applicable.

(2) Promptly return the submission to the WRAIR investigators/POCs if incomplete or additional information is needed.

(3) Concur or non-concur with the public health activity determination. Appeals must be made within 30 days in the event of the non-concurrence by Branch/Directorate Director.

d. WRAIR Institutional Official (IO) will:

(1) Provide written approval or disapproval of implementation of an emergency response. In the event of disapproval, WRAIR IO retains the authority to halt research activities.

(2) Receive copies of all determinations for public health activities.

9. Publications: Information products that are derived from public health projects are required to be reviewed by the WRAIR Public Affairs Office for clearance.

10. Points of Contact: The points of contact for this policy are the Chair, WRAIR IRB, and the Director, HSPB, at (301) 319-9940.

Signature on file

2 Encls
1. Submission Checklist
2. Determination Form

Appendix A:

Submission Checklist for WRAIR Investigators/POCs:

Complete *WRAIR Public Health Research / Non-research Determination Form* with Branch/Directorate Director's signature

Written request from requesting agency, organization, hospital, health care provider. (Has this gone through applicable channels and is it logged through operations?)

Other applicable reviews (e.g., JAG review for liability considerations; Safety/Bio-surety review)

Appendix B:

WRAIR Public Health Research / Non-research Determination Form[i]

I. Protocol Identifiers:

Title:

II. Contacts:

1. WRAIR Investigator or Point of Contact:

   Branch/Directorate:

   Email address:

   Phone:

2. Organization name, address, and phone of entity requesting public health assistance (must be authorized [e.g., federal, provincial state, territorial law or directive] to conduct public health activity):

   Name and position of contact at requesting entity:

III. Project Description:

Please describe the purpose, question, methods, and plans for use of information obtained (1-2 paragraphs; attach relevant protocol materials, if applicable):

What is the funding source?

Describe how these efforts align with the WRAIR mission as stated in Section 4. Background:

Describe the specific tasks WRAIR will perform or support in this public health effort (e.g., laboratory testing, contact tracing, public health surveillance, out-break investigation):

If applicable, please describe the plan for disposition of samples and data. If samples or data will be archived, wherever possible, obtain prospective informed consent from patients or legally authorized representatives for any future research uses of archived samples. Subsequent use of these samples for any purpose outside of this activity will require review by WRAIR HSPB prior to use.

IV. Assessment of Activity

1. Is the purpose of this systematic investigation to produce generalizable knowledge?

Yes (If yes, please submit research protocol to HSPB for IRB review. End.)
No (If no, please proceed to Q2.)

2. Does this systematic investigation involve use of any investigational drugs, biologics, or devices (e.g. in vitro diagnostics)?

Yes (If yes, please contact HSPB for further guidance. End.)
No (If no, please proceed to Q3.)

3. Does this activity support a core public health function (e.g., assessment, assurance, policy development, determination of etiology of disease)?

Yes (If yes, please proceed to Q4.)
No (If no, please submit research protocol to HSPB for IRB review. End.)

4. Is the activity conducted under the authority of in collaboration with an organization chartered to perform a public health mission (e.g., Centers for Disease Control and Prevention, Ministry of Health, Public Health Command)?

Yes (If yes, please indicate the name of the organization and proceed to Q6.)
Name of collaborating public health organization:

No (If no, please submit research protocol to HSPB for IRB review. End.)

5. Is there an *a priori* purpose of this activity to prevent or control disease or injury and improve health, or to enhance a public health program or service?

Yes (If yes, please proceed to Section V.)
No (If no, please submit research protocol to HSPB for IRB review. End.)

V. Certification (Branch/Directorate Director)

This activity meets the requirements necessary to be considered non-research and does not require IRB review.

Name of Branch/Directorate Director (print):

Signature: Date:

VI. WRAIR HSPB Concurrence

This activity does not meet the definition of research and does not require IRB review.

Name (print):

Signature: Date:

This activity appears to meet the definition of research and will require submission of a non-human subjects research determination or IRB review.

Name (print):

Signature: Date:

Date WRAIR Investigator/POC notified:

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[1] Adapted from 45 CFR 46; OHRP, Human Subject Regulations Decision Charts, February 16, 2016 https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html; Otto et al, *Am J Public Health*, 2014;104(4):596-602; and CDC, Distinguishing Public Health Research and Public Health Non-research, 2010, https://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf.