Appendix B

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

I. Protocol Identifiers:

Title:

Version/Date:

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 WRAIR Commander's IRB Policy #10, Section 5, Background:

Describe the specific tasks WRAIR will perform or support in this public health effort (e.g., laboratory testing, contact tracing, public health surveillance, outbreak 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, or 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 Q5.)
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/Center/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:

[i] 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 Nonresearch, 2010, https://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf.