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

FCMR-UWZ (1200B) 10 April 2024

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

SUBJECT: WRAIR Policy #32, Use of Existing Human Information and/or Human Biological Specimens

1. References.

a. Commerce and Trade, 15 United States Code (U.S.C.) §§ 3701-3724, (2017).

b. National Defense, 32 Code of Federal Regulations (C.F.R.) §§ 219.101-219.124, (2108).

c. Food and Drugs, 21 C.F.R. §§ 50.1-50.56 and §§ 56.101-56.124, (2018).

d. Public Welfare, 45 C.F.R. §§ 46.101-46.505, Revised Common Rule, (2018).

e. Belmont Report (Ethical Principles and Guidelines for the Protection of Human Subjects of Research), 1979.

f. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP) (Guidance on Engagement of Institutions in Human Subjects Research), 16 October 2008.

g. DHHS OHRP (Guidance on Research, Coded Private Information or Biological Specimens), 16 October 2008.

h. Secretary's Advisory Committee of Human Research Protections (SACHRP), letter (SACHRP Letter to the HHS Secretary: Recommendations from SAS & SOH), Attachment D (FAQs, Terms and Recommendations on Informed Consent and Research Use of Biospecimens), 24 January 2011.

i. Department of Defense Directive (DODI) 3216.02 (Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research), 29 June 2022.

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

k. AR 70-41 (International Cooperative Research, Development, and Acquisition)

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*This supersedes WRAIR Policy #32, dated 27 January 2022.

l. AR 70–57 (Military–Civilian Technology Transfer).

m. Message, ALARACT 031/2008 (Army Human Subjects Protection Requirements), 141557Z February 2008.

n. WRAIR Policy #24 (Submission Requirements for Human Subjects, their Information or Biospecimens)

o. WRAIR Policy #25 (Determination that an Activity is Research Involving Human Subjects).

p. WRAIR Policy #26 (Initial and Continuing Human Subjects Research Protection Education Requirements).

q. WRAIR Policy #31 (Final Approval Authorization for Human Subjects Research Protocol Implementation).

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 is a supplement to WRAIR Policy #25, Determination that an Activity is Research Involving Human Subjects. This policy establishes the criteria by which the WRAIR determines whether existing human information (data) and/or existing human biological specimens (or “bio-specimens”) can be used for future projects, whether as new, novel research or a continuation of past research projects, and the minimum institutional requirements for such use.

4. Definitions.

a. Anonymized: For the purposes of this policy, “anonymized” refers to coded human information (data) or bio-specimens, for which the key or link to decipher the code has been destroyed.

b. Anonymous: For the purposes of this policy, “anonymous” refers to human information (data) or bio-specimens, for which no identifying private information was initially collected.

c. Broad Consent: Broad consent is an alternative to the informed consent and applies only for the storage, maintenance, and secondary research use of identifiable

private information or identifiable bio-specimens (collected for either research studies other than the proposed research or nonresearched purposes).

d. Cadaver: A deceased person or portion thereof, and is synonymous with the terms "human cadaver" and "post-mortem human subject" (PMHS). The term includes organs, tissue, cells, eyes, bones, arteries or other bio-specimens obtained from an individual after death. The term "cadaver" does not include portions of an individual person, such as organs, tissue or blood, that were removed while the individual was alive (for example, if a living person donated tissue for use in future research protocols, that tissue is not considered a "cadaver" under this policy, regardless of whether the donor is living or deceased at the time of tissue use).

e. Coded: Coded is defined in OHRP Guidance on Research Involving Coded Private Information or Biologic Specimens as:

(1) Identifying information (for example, name, initials, social security number, address, etc.) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or bio-specimens pertain has been replaced with a number, letter, symbol, or combination thereof (such as, the code); and

(2) A key or link to decipher the code exists, enabling linkage of the identifying information to the private information or bio-specimens.

(3) Private information or bio-specimens are considered to be *individually identifiable* when they can be linked to specific individuals through coding systems by any member of the research team or management of that research team.

f. Engaged in Human Subjects Research: An institution is engaged in research involving human subjects if its employee(s) (i) obtains information or bio-specimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or bio-specimens for research purposes; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable bio-specimens for research purposes.

g. Existing Human Information or Bio-specimens: For the purposes of this policy, existing information and bio-specimens means human information and bio-specimens that remain after a study is conducted (whether at WRAIR or through collaborative efforts) where all planned analyses and study participant follow-up has been completed. This includes existing information and bio-specimens from past research studies, public health efforts, clinical discards, service samples, etc.

h. Future Use: For the purposes of this policy, this means use not covered under a currently open and IRB-approved protocol where subject participation is still active and ongoing. Information (data)/bio-specimens must already exist.

i. 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.

j. Identifiable Bio-specimen: A bio-specimen for which the identity of the subject is or may readily be ascertained by any member of the research team or management of that research team, or is associated with the bio-specimen.

k. Identifiable Private Information: Private Information for which the identity of the subject is or may readily be ascertained by any member of the research team or management of that research team, or is associated with the information.

l. Institutional Official (IO): Individual ultimately responsible for the implementation of the U.S. Department of Health and Human Services (DHHS) Federal wide Assurance and the DOD Assurance of Compliance for the Protection of Human Research Subjects and the associated HRPP at an institution engaged in research involving human subjects. Within the USAMRDC, the Commander of the institution/organization engaged in research is the IO.

m. Interaction: For the purposes of this policy, interaction includes communication or interpersonal contact between investigator and subject.

n. Intervention: For the purposes of this policy, intervention includes both physical procedures by which information or bio-specimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

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

p. Research Involving Human Subjects: Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual about whom an investigator 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.

q. WRAIR Point of Contact (POC): An individual, affiliated with WRAIR or its Directorates, who is responsible for submission of protocol documents to the HSPB over the lifecycle of the study as new protocol actions are processed, remains in

continual communication regarding the study to regulatory authorities, and directs study execution wherein WRAIR is participating. This individual is generally the lead WRAIR investigator on the protocol but is not the overall study Principal Investigator (PI). The POC can be the site PI, a clinical coordinator, program manager, associate investigator, or other individual involved in the study in a scientific, academic, or administrative capacity.

5. Background. As new technologies become available and new research questions arise, it is desirable to be able to utilize existing human information (data) and human biological specimens in research projects. These existing bio-specimens and data represent an invaluable resource for current and future research on global human health. WRAIR Research Teams have long-standing relationships and productive scientific collaborations with many outside parties. In an effort to be transparent and respectful of WRAIR's partners, whether within the U.S. or internationally, it is desirable to obtain their input with regard to uses of collaboratively collected, now existing human information (data) and/or human bio-specimens.

a. The use of existing human information (data) and/or bio-specimens offers a way to answer scientific questions that otherwise could not be addressed if collected at specific time points or following specific exposures. Without this use, the WRAIR would need to put additional human subjects at risk to obtain samples by enrolling them into new studies.

b. This policy is an effort to describe the standard evaluation pathway and requirements for the allowance of future use of human information and human bio-specimens that remain after a study is conducted (whether at WRAIR or through collaborative efforts). Wherever possible, subject/patient identifiers should be removed from bio-specimen labeling and existing databases, to ensure privacy and confidentiality.

6. Applicability and Scope. This policy applies to the use of existing human information (data) and/or existing human biological specimens, including those from past research studies, public health efforts, clinical discards, service samples, etc. Additionally, policy applies to all personnel employed (Federal or contractor) by the WRAIR and its Directorates, who propose to use existing human information (data) and/or human biological specimens, which is not already covered by an open/active, Institutional Review Board (IRB)-approved protocol.

7. Policy.

a. For researchers who intend to use existing human information (data) and/or bio-specimens, which are not covered by a currently open/active, IRB-approved protocol, the following will be considered in relationship to the requested use:

(1) origin of the bio-specimens and/or data

(2) channel by which they were obtained (IRB-approved research study, clinical discards, public health efforts, etc.)

(3) current location and responsible steward

(4) nature of the proposed secondary research

(5) sponsor requirements for the new or continued use

(6) determination as to whether this project reasonably falls within the scope of the original research (as described in the consent form, if one existed)

(7) imposition of any new or significantly greater risks (including privacy risks) which were not described in the initial consent form, and

(8) cultural acceptability; known concerns of the study population(s) (from whom the bio-specimens or data originated) about the proposed new use.

b. In general, the evaluation of this type of research request to determine whether additional informed consent is required, would vary depending upon the origin and intent of the previous and current work. A review of the agreement by which WRAIR received the existing human data and/or bio-specimens will also be completed.

c. At a minimum, WRAIR regulatory determination (IRB/HSPB review or deferral, as appropriate) is required prior to the execution of any work, per WRAIR Policy #25. The category of research (exempt, “research not involving human subjects”, minimal risk, or in rare cases when using existing human information (data)/bio-specimens, greater than minimal risk) will be determined according to WRAIR Policy #25 and not by the submitting party.

d. This requirement also applies to studies in which WRAIR investigators are supporting in a peripheral capacity (such as, performing laboratory assays, data mining, serving as consultants, etc.). Human data and/or bio-specimens must be existing (“on-the shelf”), and the originating protocol must be closed; otherwise, WRAIR must be added to the collaborator’s active protocol, with roles and responsibilities included.

e. For collaboratively collected human information (data)/bio-specimens, additional considerations may apply:

(1) previous and new business agreement allowances

(2) collaborating Institution’s authorization (bio-specimens/data origination)

(3) local IRB (or IRB/Regulatory office) approvals (determinations), or deferrals

(4) USAMRDC Human Research Protection Office (HRPO) approval, as appropriate

f. This may be reviewed on a study-by-study, institutional, or country-by-country basis. The IRB (or administrative office) of the collaborating institution will decide on the approach at their institutions with regard to use allowances. Examples of considerations are included in Appendix A.

g. Protocols are to specifically contain language that will inform subjects that their human information (data) and/or bio-specimens may be used in future research projects, as applicable. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable bio-specimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to the informed consent requirements or in addition to the original informed consent requirements. Per the new Common Rule (45 C.F.R. §§ 46.101-46.505), broad consent for future use is preferred. The same review pathway will be used as described above. If the protocol, consent and corresponding business agreement are silent as to the future allowances, the Exemption Determination Officer (or designee) and/or IRB Chair (or designee) can make the decision as to whether a “reasonable person” could have assumed future use. Consenting and/or a waiver of consent may be requested but is not the default if the human information/ bio-specimens are coded/anonymized.

h. Research in which the subject is/was a fetus, in-utero or ex-utero (including human fetal tissue/cells) is a unique category and may require review by the full WRAIR IRB, MRDC HRPO, and/or AHRPO. Investigators are encouraged to seek guidance early with regard to this type of request. Cord blood or materials derived from a placenta are not considered fetal tissue. Due to state and federal laws that govern research use of fetal tissue, confirmation will be required that the institutional review determined that: the written consent of the mother was obtained; the fetus can be used for research; the use of fetal material is required for the research and other materials cannot be substituted; and the source of the materials are documented (institution, clinical providers, non-profit repositories, etc.).

i. Health Insurance Portability and Accountability Act (HIPAA) authorizations or waivers may also be required, as applicable (for example, collaborations with covered entities, such as Military Treatment Facilities).

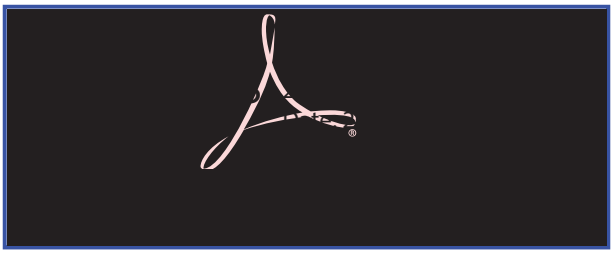
j. Appendix B Cover Memo and Submission Form are to be used for all submissions using existing human information and bio-specimens. Overseas Directorate Directors

can opt to use this form as supplemental, since host nations may require a full protocol submission. The Directorate's project plan should be discussed with HSPB.

k. Research teams are encouraged to meet with a Human Subjects Protection Branch representative to discuss their projects prior to filling out Appendix B (or full project/protocol submission) to map the tentative review process.

l. Once a determination has been made, no changes, amendments, or addenda may be made to the protocol without prior review and approval by the WRAIR IRB, and the USAMRMC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), as applicable. As part of the WRAIR IRB's responsibility to confirm research is being conducted in a manner where the conditions of the federal regulations, DoD Instruction, IRB and Institutional policies are being met, this protocol may be selected for post approval compliance monitoring.

8. 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.



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1. Appendix A:
   Examples of Consideration
2. Appendix B:
   Cover Memo/Submission

Appendix A: Examples of Considerations

Examples to consider in preparing a submission using existing human information (data) and/or bio-specimens:

1. Channel by which human information/bio-specimens were obtained (IRB approved research study, clinical discards, public health efforts, etc.)

a. Was broad consent or informed consent obtained? (Provide a copy)
b. If informed consent was obtained, what permissions for use were provided by the research subjects?
c. What were the protocol allowances for this use?
d. Does this use for the proposed project affect the rights and welfare of the subjects?

2. Current location and responsible steward. There can be complex issues of ownership of bio-specimens and intellectual property considerations with regard to discoveries made using human information/bio-specimens. How will the investigator handle future third-party access?

3. Sponsor requirements for the new or continued use should be gathered prior to submission.

4. Will research results be returned to subjects and if so, how and when? How will incidental findings be managed/reported?

5. Determination as to whether this project reasonably falls within the scope of the original research (as described in the objectives of the study or in the informed consent form, if one existed). What is the nature of the proposed secondary research?

6. Imposition of any new or significantly greater risks (including privacy risks) which were not described in the initial consent form.

Special considerations might include, but are not limited to:

a. Genetic studies where the findings might involve risks that could harm an individual, a family, a group or community. These risks could include psychological, social, or economic harm. Examples of this might include an employer or insurance company learning of a genetic predisposition for a particular disorder and refusing employment or coverage. Please note that research involving large-scale genomic data (LSGD) collected from DoD-affiliated personnel are subject to DoD Component security review and DOHRP approval, including the secondary use or sharing of de-identified data or specimens.

b. Bio-specimens from children who are now adults in secondary research.

7. Cultural/religious acceptability. Known concerns of the study population(s) (from whom the bio-specimens originated) about the proposed new use. Also understand:

a. Role of community advisory boards

b. Assessing community risk

8. Collaborating Institution's authorization requirements (human information/bio--specimens origination). International partners may require import/export permits for use of the samples or data.

9. Know the requirements of the local IRB (or regulatory office) and how to gain approvals (determinations), or deferrals for new collaborators.

10. USAMRDC OHARO OHRO approval may also be needed, depending upon location of research, funding, vulnerable populations, and other considerations (refer to USAMRDC Command Policy).

11. Understand business agreement (past and present) allowances, as well as those described in the protocol.

Appendix B: Cover Memo and Submission Form

THE Highlighted Areas on this memo are to be tailored to your submission** REMOVE THIS SENTENCE.

FCMR-XXX-XX Date

MEMORANDUM THRU

Director X, Center/Branch/Directorate

FOR Director, Walter Reed Army Institute of Research Human Subjects Protection Branch, 503 Robert Grant Avenue, Silver Spring, MD 20910

SUBJECT: Request for Human Subjects Research Review and Determination

1. Request submission for review of new research project titled "X" (version, date), PI, institution affiliation. Information (data) and/or human biological specimens are currently existing/on-the-shelf and the WRAIR research team does not have access to participant identifiers.

2. The submission has been verified by the Principal Investigator (PI) and Center/Branch/Directorate Director. Please process for review, as appropriate, as this project is being submitted in accordance with See WRAIR Policy #25, Human Subjects Research Review and Determinations. *(Note: If the Center/Branch/Directorate Director is named as an investigator on the project WRAIR Scientific Review will be required as her/his participation in the project and sign off on the scientific validity would be considered a conflict of interest, The protocol will be forwarded to the WRAIR Chief Science Officer and Chair, WRAIR Scientific Review Committee, if applicable, for compliance with scientific review requirements (see Scientific Review of Human Subjects Research Protocols SOP UWZ-002).)*

3. The primary objectives are:

4. The following documents are attached:
   a. Completed Submission Form
   b. Copy of Project/Protocol (version X, dated X)
   c. Copy of Informed Consent Document from which the human information/bio-specimens were originally collected
   d. Copy of the PI's and other listed investigators' current signed and date CV and human subjects protection training certificate

e. *List other relevant supporting documents (e.g. associated taskers, funding documents, list of collaborators, letter from OCONUS Ministry of Health requesting assistance, permission letter from the PI of the original study for use of the human information or bio-specimens, etc.)*

f. *Copy of local, collaborator's, etc., institution determination of engagement in human subjects research*

5. As the PI, I will carry out the project as outlined in the attached request form.

6. The point of contact for this action is undersigned at telephone number XXXX, Email XXXX.

SIGNATORY
RANK
ROLE

Center/Branch/Directorate Director Approval

This study is:
- ●Scientifically feasible and valid,
- ●Militarily relevant, and
- ●Appropriately resourced (funding, personnel, equipment, etc.)

I certify this individual has the requisite qualifications to execute this project.

SIGNATORY
RANK
Center/Branch/Directorate Director

FCMR-UWZ (1200B)
SUBJECT: WRAIR Policy #32, Use of Existing Human Information and/or Human Biological Specimens

WRAIR Human Subjects Protection Branch
Request for Human Subjects Research Review and Determination

Section A: Instructions. Use this form for projects requiring human subjects research review and determination. Information (data) and/or specimens must be currently existing/on-the-shelf. Enter project information in the spaces provided to complete all applicable sections of the form. Submit this completed form and the project documents to the WRAIR HSPB electronic mailbox at: usarmy.detrick.medcom-wrair.mbx.hspb@health.mil.

Reminder: If appropriate, has a consultation with HSPB occurred to determine that this is the appropriate pathway for submission of this project?

Principal Investigator/ WRAIR Point of Contact, if not Lead Investigator (name, degrees)	**Dept./Branch/ Center**	**Phone**	**E-Mail**	**Status (Staff: Military, GS, Contractor)**

PROJECT/PROTOCOL TITLE:

VERSION/DATE:

FUNDING SOURCE(S) (response required):

A. If internal funds are being used, list the type fund(s) and accounting processing code (WBS)

B. If extramural, what is the name of the sponsor and are there any other funding sources?

Provide the grant/contract number/accounting processing code (WBS), if available (Example: NIH R01 Grant, CDMRP, GSK CRADA, etc):

Note: *protocols/projects must have a funding source identified in order to be reviewed by the HSPB.*

STUDY/PROJECT TEAM. Identify all study team members, collaborating institutions, and their roles and responsibilities.

List Study Team Members: (*add additional rows, as needed*)

Study Team Members	Study Roles and Responsibilities
Name: Contact Information: Affiliated Institution:	Study Role(s):
Name: Contact Information: Affiliated Institution:	Study Role(s):

List Collaborators/Partners or Other Involved Institutions:

If applicable, please provide the following additional information:

Collaborator/ Partner/Involved Institution	DHHS or DoD Federalwide Assurance # (Click here to search)	Name of Reviewing IRB or Ethics Committee	IRB Approval/ Determination Status* *(Indicate: Yes, No, Pending)*	IRB Determination **	IRB Approval Date
Name: Contact Information: Affiliated Institution: Study Role(s):				Choose an item.	Click here to enter a date.
Name: Contact Information: Affiliated Institution:				Choose an item.	Click here to enter a date.

Study Role(s):					

IRB Approval*: Indicate whether IRB approval has taken place or is pending. If there are any Institutional Agreements for IRB review planned, describe in the space provided.

IRB Determination**: Indicate the determination (exempt, not greater than minimal risk, greater than minimal risk) made by the IRB or the institution during the initial review of the protocol, to include "research not involving human subjects" determinations from participating institutions that do not have access to identifiable human information (data) or materials. If not available, please contact the respective IRB office for assistance prior to submission to the HSPB.

SECTION 1: PROJECT INFORMATION

A. Is this activity initiated by:

- ☐ Person(s) within the institution (WRAIR/WRAIR Directorate is the lead organization.)
- ☐ Person(s) external to the institution
- ☐ Cooperative group/Consortium
- ☐ External sponsor/manufacturer
- ☐ Student/class project
- ☐ Other, specify:

B. Briefly summarize the proposed activity. (Describe the primary purpose/specific objectives, including background information, and any military relevance the project might have. Explain how objectives will be accomplished and the rationale for the proposed project. Include a statement as to whether you anticipate presenting or publishing the findings. If the project involves coded private information (data) or bio-specimens include detailed information regarding the number and type of bio-specimens, the number of subjects whose data will be used and how these will be labeled. Include the disposition plan for any remaining bio--specimens.)

C. Describe specific tests/assays, methods that will be used for the bio-specimens. Provide package inserts for test kits and rapid diagnostic tests (RDTs) that will be used. Clarify if CLIP/CLIA tests and whether results will be provided to the subjects/patients.

D. Include a statement as to whether the bio-specimens or information/data support the marketing of a FDA regulated drug/biologic/device and if this project is in support of a FDA application, please state who will be serving as the Sponsor for the application.

E. Describe the specific aspect of the activity that involves humans (contact with human populations, records/spreadsheets with human data, or use of bio-specimens).

F. Describe the source/provider of the human information or bio-specimens and/or how such will be obtained.

SECTION 2: DETERMINATION OF "RESEARCH"

A. Do the proposed activities involve a systematic approach? A "systematic" approach involves a predetermined method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory. A systematic approach incorporates collection of data, either quantitative or qualitative, or bio-specimens, and analysis.

☐No ☐ Yes

If No, explain why the proposed activities do not involve a systematic approach:

B. Is the intent of the proposed activities to develop or contribute to generalizable (scholarly) knowledge? Activities 'designed to develop or contribute to generalizable knowledge' are those activities designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations beyond the specific study population), inform policy, or generalize findings.

☐No ☐ Yes

If No, explain the intent of proposed activities and explain how the proposed activities are not intended to contribute to generalizable knowledge:

If Yes to either of the above questions, the proposed activity generally constitutes research. Proceed to Section 3.

If No, the proposed activity generally does not constitute research. Proceed to Section 4.

SECTION 3: DETERMINATION OF "HUMAN SUBJECT"

A. Does the research involve obtaining information about living individuals (or if involving decedents, can the research impact living individuals)?

☐No ☐ Yes (If not sure, please contact HSPB)

B. Does the research involve intervention or interaction with a "human subject"?

☐No ☐ Yes (If not sure, please contact HSPB)

C. Does the research involve access to identifiable private information?

☐No ☐ Yes (If not sure, please contact HSPB)

D. Are human information (data)/bio-specimens received by the Investigator(s) with identifiable private information? (Examples include Social Security Numbers, country Identification Numbers, names, initials, (or other indicators: home address, marital status, zip codes, dates of collection, etc.)

☐No ☐ Yes (If not sure, please contact HSPB)

E. Are the human information (data)/bio-specimen(s) coded such that a link exists that could allow the human information (data)/bio-specimen(s) to be re-identified?

☐No ☐ Yes (If not sure, please contact HSPB)

If yes, provide the written agreement that prohibits the PI and his/her staff access to the link, or a standard operating procedure that exemplifies how this prohibition is being managed.

SECTION 4: CODED/ ANONYMOUS/ ANONYMIZED HUMAN INFORMATION (DATA)/ BIOSPECIMENS

A. Is the study under which the samples or data collected still open?

☐No ☐ Yes

If yes, what is the current status?

☐ Closed to enrollment but volunteer activities continue

☐ Closed to enrollment and study activities have been complete as of *(date)*

Provide a detailed description of why informed consent for the proposed use cannot be obtained. Please be specific:

FCMR-UWZ (1200B)
SUBJECT: WRAIR Policy #32, Use of Existing Human Information and/or Human Biological Specimens

B. Does the project involve pre-existing coded, anonymous or anonymized human data/bio-specimens? (NOTE: EXISTING means materials/data are already "on the shelf" or archived when the study is proposed)

☐No ☐ Yes (If not sure, please contact HSPB)
If yes, please provide the following information:

Human Information (data)/Bio-specimens:

Describe the number and type of coded data/bio-specimens you will use and/or access and how these will be labeled. Please be specific:

Source of Human Information (data)/Bio-specimens:

1. Where will you obtain/access the human information (data)/bio-specimens? Please be specific (i.e., identify the providing institution, repository, colleague, etc.).

2. Does this research project involve secondary use of coded human information (data)/bio-specimens obtained from a research protocol in which subjects provided informed consent for the collection of their bio-specimens?

☐ Yes. If 'Yes' provide the following information:
- Protocol title ;
- WRAIR Protocol Number (if applicable) ;
- Protocol status (open or closed) ;

Note: a. Include the collection consent form in your submission for review.
b. If samples/data were not obtained under a WRAIR protocol, include a copy of the original
protocol and local IRB/ERC approval(s) of that protocol in your submission).
c. If the subjects were given a choice in the original study consent form to allow for future use, verify with the original study PI that only those samples/data are provided where the subjects gave consent for future use.

☐ No. If no, explain here *(e.g. bio-specimens collected for clinical purposes or public health outbreaks).*

3. If the coded human information (data)/bio-specimens obtained did not come from a research protocol, did they come from any of the following sources *(Check all that apply and include any applicable clinical consent forms in your submission for review):*

i. Repository ☐ Yes. ☐ No.

ii. Surgical/Clinical Discard ☐ Yes. ☐ No.

iii. Clinical Registry ☐ Yes. ☐ No.

iv. Deceased Individuals (e.g., autopsy, tissue donation program)

☐ Yes. *(Contact HSPB staff for cadaver research submissions)*
☐ No.

v. Publicly Available Source ☐ Yes. ☐ No.

vi. Outbreak Investigation ☐ Yes. ☐ No.

vii. Other. ☐ Yes. ☐ No. If Other, Explain: ( )

4. Does the consent form (clinical or research) used for the collection of the human information (data)/bio-specimens include any limitations or prohibitions on future use of data/bio-specimens? *(Include the consent form in the HSPB submission)*

☐ Yes. If yes, explain ( )
☐ No.
☐ The consent form is unavailable. *Note: If unavailable, HSPB may require additional certification(s) for permissible use of data/bio-specimens.*
☐ There was no consent form, as this was an outbreak investigation or clinical laboratory where only verbal consent/permission was obtained. *Note: A copy of the originating institution's policy/procedures regarding obtaining permission/consent may need to be submitted.*

5. Did all of the human information (data)/bio-specimens exist when the research was proposed?

☐ Yes. If yes, identify their current location and the responsible steward *(e.g. central repository, lab, pathology department, collaborating institution, etc.)*

☐ No. Explain:

6. For pre-existing human information (data), documents, medical records, or database records, does the data include information of a sensitive nature? (*e.g. about drug and alcohol use, sexual practices, child or spousal abuse, or other information that could be criminal or damaging to one's financial or social standing, employability, insurability, or psychological well-being*)

☐ Yes. If yes, explain
☐ No.

FCMR-UWZ (1200B)
SUBJECT: WRAIR Policy #32, Use of Existing Human Information and/or Human Biological Specimens

Identifiability of Human Information (data)/Bio-specimens:

1. Will you/your research team obtain information that directly identifies the original data/bio-specimens donor?

☐ Yes. If yes, explain
☐ No.

2. Will the data/bio-specimens obtained by you/your research team contain codes linking the data/bio-specimens back to the original donor?

☐ Yes.
☐ No.

- If 'Yes', will the key to the code ever be made available to you or any investigator collaborating with you on this research?

☐ Yes. Please explain
☐ No.

3. Are any personnel involved in the proposed use of these data/bio-specimens also involved in the original collection of the data/bio-specimens?

☐ Yes. If yes, please explain in what capacity.
☐ No.

Institutional Review and Determination Status (if applicable):

Has the use of human information (data)/bio-specimens as proposed in the WRAIR conducted or supported project been reviewed by a collaborating institution? Please select one of the following:

☐ Yes. If yes, how was it reviewed at the collaborating institution?

a. ☐ The IRB reviewed the project as an amendment to an ongoing protocol. *(Submit a copy of the current IRB-approved protocol and amendment to incorporate the WRAIR conducted or supported activities.)*

b. ☐ The IRB reviewed the project as a new protocol. *(Submit a copy of the IRB submission and applicable bio-specimen collection consent forms for review.)*

c. ☐ Other Institutional review. Describe:

☐ No. The use of bio-specimens/data in the WRAIR conducted or supported project has not been reviewed by the collaborating institution because *(Please explain):*

FCMR-UWZ (1200B)
SUBJECT: WRAIR Policy #32, Use of Existing Human Information and/or Human Biological Specimens

C. Does the study involve prospectively collecting human information (data) or bio-specimens from clinical activities (i.e., epidemiological consultations, surveillance, or command-directed assessment)?

☐No ☐ Yes ☐ Not sure

If yes, provide the following information, as applicable:
- Copies of any associated taskers;
- Request letter/memorandum from the OCONUS Ministry of Health asking for assistance.

SECTION 5: OTHER CONSIDERATIONS

A. Does this research involve decedents (individuals who have died)? (Reference: HIPAA & WRAIR Cadaver Policy)

☐No ☐ Yes (If not sure, please contact HSPB)

If yes, please describe:

B. Are you using bio-specimens that contain biohazardous/infectious agents?

☐No ☐ Yes (If not sure, please contact HSPB)

If yes, has a biosafety committee reviewed this project?

☐No ☐ Yes

If yes, describe the safety measures that will be followed:

C. Were the bio-specimens and/or data collected from subjects in countries outside of the United States?

☐No ☐ Yes (If not sure, please contact HSPB)

If yes, approval from the local country Ethical Review Committee (ERC)/IRB that initially approved the research under which the bio-specimens and/or data were collected, may be required. Contact the local ERC/IRB to obtain their approvals and export permits, as appropriate, and provide copies of these approvals and permits with this submission.

SECTION 6: Other

FCMR-UWZ (1200B)
SUBJECT: WRAIR Policy #32, Use of Existing Human Information and/or Human Biological Specimens

The WRAIR PI/Point of Contact (POC) has the responsibility to obtain all business agreements prior to initiation of any work with partners/collaborators or contracted services under this project. This includes any transfer of data. Failure to obtain business agreements prior to initiation could result in sanctions or disciplinary actions for the Branch/Directorate Director and WRAIR PI/POC. The IRB and/or HSPB will review business agreements as part of monitoring visits to ensure they were obtained as required and report to the WRAIR Commander as to adherence to this requirement.

Seek guidance from the Research Program Office (RPO) as to whether a business agreement is needed for this project.

USAMRDC Human Research Protection Office (HRPO) review and approval may be required for certain projects. This requirement depends upon funding, study location, the inclusion of samples from vulnerable populations, external collaborators, etc.

By signing the below, the signatories are affirming that the above information is accurate and applicable documents are in place for the submission of this study.

Signatures/Dates:

_____	_____	_____	_____
PI/WRAIR POC Signature	Date	Center/Branch /Directorate Director	Date

_____	_____
Print Name	Print Name

SECTION 7: Principal Investigator/WRAIR POC Agreement

1. I agree to follow this project description as submitted to the HSPB/IRBs/ERCs.

2. I certify that I, and the study team, have received the requisite training to conduct this project. A file of the study team's current Curriculum Vitae will be maintained with the investigator's project file.

3. I certify that all individuals listed on the project and other members of the study team have met the training requirements per WRAIR Policy #26, Initial and Ongoing Human Subjects Protection Education and Training Requirements. A file of the study team's current Human Subjects Protection Training certificates will be maintained with the investigator's project file.

3. I will ensure that any outside collaborators consult with their respective institutions to obtain the requisite approvals or determinations.

4. I will not amend/modify the project to change study objectives, change investigators and/or roles/responsibilities, change the source of samples/data, or change access to information that could identify individual donors, without first submitting an amendment to the WRAIR Human Subjects Protection Branch (HSPB) for a determination as to whether or not the project continues to qualify as research not involving human subjects.

5. *As applicable.* I, or the study staff, do not have access to the code linking a participant and his/her bio-specimen (or data) and will make no attempts to individually identify a study participant. Should I, or the study staff, gain access to the code, I will promptly notify the HSPB, IRB(s)/ERC(s).

6. I will ensure that the data (and/or bio-specimens) are maintained in accordance with the data (and/or bio-specimen) disposition outlined in the protocol. Any modifications to this plan should first be reviewed and approved by the applicable IRBs/ERCs.

7. Unanticipated problems involving risks to subjects or others (i.e., a breach of confidentiality) and significant deviations will be promptly reported (within 48 hours of the Principal Investigator by telephone (301-319-9940), fax (301-319-9961) or email (usarmy.detrick.medcom-wrair.mbx.hspb@health.mil to the WRAIR HSPB, and then will be followed-up in writing within 10 working days from awareness of the problem. Significant Deviations are defined as non-adherence to the approved protocol that has the potential to affect the rights and welfare of the research participant, to increase the risk to the research participant, to change the willingness of the volunteer to continue participation, or to compromise the integrity of the study data in such a way that the study objectives may not be achieved.

8. I will immediately report to the WRAIR HSPB knowledge of any pending compliance inspection by any outside governmental agency.

9. I agree to maintain adequate and accurate records in accordance with IRB policies, Federal, state and local laws and regulations.

Signed: _____ _____
Principal Investigator/WRAIR POC Date

_____
Print Name

SECTION 8: Human Subjects Protection Branch Exempt Determination Official Use Only

WRAIR Protocol Number

The information contained within this submission is:
☐ Complete
☐ Incomplete (specify below)
Comment:

_____
_____

WRAIR's role in this activity is:

☐ Not Research. (Examples: Quality Assurance, Program Evaluation, Public Health Practice, etc)
☐ Research not involving human subjects.
☐ Exempt Research
Comment:

_____
_____

A determination was made that WRAIR's participation in this project does not require review by the WRAIR IRB in accordance with WRAIR Policy #25, Determinations that Research is involving Human Subjects, as WRAIR's participation in this project involves activities for which the project team does not have access to any identifiable or linking subject information. Therefore, this research activity does not meet the definition of research involving human subjects and
32 CFR 219 does not apply.

If bio-specimens/data are to be retained, include in the closeout notification information regarding where bio-specimens/data will be stored, for how long, how they are labeled, who will have access, etc. If any remaining bio-specimens/data are to be destroyed upon completion of this project, a log of what was destroyed and witness to that destruction needs to be maintained with the project file.

The WRAIR HSPB reserves the right to review the research project records and re-assess the research not involving human subjects research determination. A closeout notification must be submitted to the WRAIR HSPB upon completion of this project.

_____ _____
Exempt Determination Official/WRAIR IRB Chair/Designee Signature Date

_____
Print Name

FCMR-UWZ (1200B)
SUBJECT: WRAIR Policy #32, Use of Existing Human Information and/or Human Biological Specimens

(The signature above constitutes a formal determination from the WRAIR HSPB Exemption Determination Official (EDO) or WRAIR Institutional Review Board.)

OR:

☐ Research involving human subjects; therefore, **submission of a full protocol and submission packet to the WRAIR IRB is required.**

A determination was made that WRAIR's participation in this project does require review by the Walter Reed Army Institute of Research WRAIR (IRB) in accordance with WRAIR Command Policy Memorandum 2019-40, as
32 CFR 219 does apply.

_____ _____
Exempt Determination Official/WRAIR IRB Chair/Designee Signature Date

_____
Print Name