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

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

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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:

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.

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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):*

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

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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

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(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