Required Elements for an "Exempt" Human Use Protocol to Study Pre-Existing Data or Specimens

All exempt protocols are subject to scientific review as per WRAIR guidelines.

NOTE: ***EXISTING means research materials are already collected or archived when this research effort is submitted.***

Cover Memo:
Provide a memo, thru the Department Chief and Division Director for the Director, Division of Human Subject Protection, which has been signed and dated by the Principal Investigator.

Protocol Title:

Principal Investigator:
Provide affiliation (include Department, Division) and contact information.

Other Significant personnel:
List the names of other personnel who will have significant involvement in the study (associate investigators, consultants, study coordinator, statisticians).
Briefly describe roles and responsibilities of study personnel.

Study Location:

Collaborating Institution(s):

Funding Source (s):

Primary Purpose/Objectives of the Study:
Also, do you anticipate presentation or publication of findings?

Significance of the study:
Include any military relevance the study might have.

Source of Pre-existing Human Data or Specimens:

- If from **research conducted at WRAIR or its Special Foreign Activities**, provide protocol title, WRAIR # and current protocol status (open or closed). Also provide where data/specimens are currently stored and who is POC for that archive.
- If from a **purchase through a commercial source**, provide documentation of the product (package insert, website listing) and procurement mechanism, such as cancelled order, etc. If the commercial source collected the specimens or data utilizing a human use protocol and/or written informed consent, a statement to that effect is appreciated.

- If from **the DoD Serum Repository (DoDSR)**, provide a copy (or a draft copy) of the request to DoD Serum Repository for specimens or a support letter from repository director at AMSA/USACHPPM.
- If from **a public health/epidemiology activity** (such as an outbreak investigation), provide documentation of the public health activity (and tasked if available) and describe how that data specimens were obtained and what consent was obtained from subjects, if any. Describe the institution and POC where data/specimens are currently stored, and who owns the specimens.
- If from **research conducted outside WRAIR**, provide protocol title, current status, and institution and POC where data/specimens are currently stored, and who owns the specimens. Attached a current or final copy of that IRB-approved protocol and latest English Informed Consent document (including consent for specimen storage and future use) as appendices, as well as IRB approval letter(s).

{If data or specimens are to be obtained from the DoDSR or an outside institution, contact ORTA to assist in preparation of a Data Use Agreement (DUA) or Commercial test Agreement (CTA), as appropriate, to allow WRAIR to accept the data or specimens and under what restrictions. This will need to be provided to ORM before WRAIR study implementation, but IRB review and approval may proceed.}

Study Design/Methods:
Briefly explain how objectives will be accomplished. Describe specific assays, methods that will be used (referencing published papers, SOPs, as appropriate). Briefly describe data analysis methodology. Note: This information may be provided as an attached project proposal or other supporting document.

If you are contributing to another investigator's project, describe your contribution (e.g. a collaborator performing lab assays).

Ethical Considerations involving **the use of previously existing data, documents, medical records, or database records:**

- Confirm whether the information is existing or will be prospectively collected.
- Describe if any data is Private Health Information (PHI) as defined by HIPAA
- Describe whether any information is 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).
- Describe how samples or data will be labeled and coded.
- Describe what links the information to be used in this study to specific individuals (links may include patient ID, SSN, name, a study code or PIN, address, photo). Describe whether any study member will have access to the link for the code, or what process prevent that from occurring
- If links to subjects still exist (coded or identified data), describe what procedures will be in place to ensure the privacy and confidentiality for study subjects.

Describe if consent was previously obtained for future use of all of the data or specimens in the study, whether additional consent from subjects is required, or whether a waiver of consent (with justification) is requested.

Describe final disposition of data and specimens after study is completed (destroyed, returned to original source, archived at WRAIR, etc.)

Reporting of Unexpected Events to WRAIR IRB:
"Unanticipated problems involving risks to subjects or others (i.e., a breach of confidentiality) and significant deviations must be promptly reported (within 48 hours of the Principal Investigator becoming aware of the problem) by telephone (301-319-9940), fax (301-319-9961) or email (wrairdhsp@amedd.army.mil) to the WRAIR DHSP, and then must be followed-up in writing within 10 working days from awareness of the problem. Any change or amendment to the protocol affecting study objectives, study design, study procedures, or significant administrative aspects (i.e., change in personnel) must be submitted to the WRAIR DHSP for acknowledgement and/or redetermination, as appropriate".

Periodic Reporting Requirements to Division of Human Subjects Protection (DHSP):
{template language}
Note: this will vary depending on the determination of whether the research involves minimal risk research, or is non-human subjects or exempt research.

Final Study Report Requirements:
{template language}

PI agreement{template language}
signature and date:

Additional Required Documentation by DHSP:
Provide **current (within the year) signed and dated CV's and/or research experience** for the *PI* and *associate investigators* on the protocol.

Provide documentation of **current human subjects protection training** for all investigators listed on the protocol as per the DHSP human subjects protection training policy.