U.S. Army Medical Research and Development Command
Office of Research Protections
Human Research Protection Office

HRPO Submission Form -- Secondary Research Involving the Use of Data/Specimens

Purpose: All United States Army Medical Research and Development Command (USAMRDC) supported secondary research involving human data, records, human tissue, or human specimens (hereafter referred as data/specimens) must be reviewed for compliance with Federal and Department of Defense (DoD) human subjects protection requirements and approved by the Office of Research Protections (ORP) prior to implementation.

Complete this ORP Human Research Protection Office (HRPO) form when the DoD-funded research activities are limited to access, use, and analysis of data/specimens, and provide it with your submission of required supporting documents. Please refer to the document, "Guidance on HRPO Review Requirements for Research Involving the Secondary Use of Data/Specimens" (located on the HRPO website: https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/hrpo) for important information on HRPO review requirements for research involving the secondary use of data/specimens.

HRPO review includes assessing the source of the data/specimens and whether the initial manner and consent for the data/specimen collection permits use in the DoD funded research protocol. The ORP must also review the use of post-mortem specimens for compliance with the U.S. Army Cadaver Use Policy.

For questions regarding ORP HRPO review requirements or assistance in completing this form, leave a message at 301-619-2165 or email usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil and a staff member will contact you.

Instructions. Please submit this completed form and all required documents via the **Electronic Biomedical Research Application (eBRAP)** portal (ebrap.org). Anyone associated with the project may submit the required documents via eBRAP, as long as they know the Principal Investigator's (PI) last name and the relevant Award Number/Log Number for the project.

eBRAP Submission Instructions:
1. Log in to your eBRAP account, or register to create a new account.
2. Once logged in, click on the drop-down arrow next to your name in the top right corner.
3. Click on "Regulatory File Drop-Off" from this drop-down menu. This will take you to the regulatory file drop-off page.
4. Anyone uploading files should input the last name of the PI holding the primary DoD award, along with the award number or log number of the relevant award for identification purposes.
5. Upload the files requested in this form, ensuring that they are correctly categorized prior to submission. Please submit documents as individual files, not as a single pdf. Ensure that file names readily identify the respective document, e.g., protocol, IRB determination.
6. If specific eBRAP questions arise, request assistance from the eBRAP help desk: 301-682-5507 or Help@eBRAP.org

NOTE: If you do not receive an acknowledgement of receipt of your submission, please send an email to your assigned HRPO Research Administrative Support point of contact or usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil requesting an update and receipt confirmation.

Click through the form, entering your information in the spaces provided to complete all applicable sections of the form.

Checklist of Required Documents to Submit with this Form. *Check all applicable documents.*

☐ Institutional Review Board (IRB) approval or Institutional Regulatory Office determination for the DoD-funded activities
☐ Protocol(s) for USAMRDC/DoD funded research
☐ DoD-specific protocol (or project description, application) limited to the DoD Statement of Work activities **(*REQUIRED*)***
☐ Core protocol (if applicable)
☐ Collection consent document
☐ Other:

USAMRDC/DoD Proposal Number:

Proposal Title:

Protocol Title *(if different from proposal)*:

Sponsor/Funding (e.g., CDMRP):

Brief Description of the Research Describe the DoD-funded activities of the research (*e.g., the DoD is funding the XX analysis of XX samples, but not sample collection*).

***IMPORTANT:** **The research protocol submitted for HRPO review MUST only include those activities funded by the DoD, as referenced in the approved Statement of Work (SOW). The HRPO will NOT review protocols submitted for DoD funded activities if such studies have been added to an ongoing/existing protocol. For the use of any data/specimens obtained from biorepositories, core facilities, or similar, the HRPO requires that investigators submit a stand-alone protocol that details ONLY the data/specimen use funded by the DoD.**

Institutional Review and Determination Status. Has the use of data/specimens as proposed in the USAMRDC/DoD funded project been reviewed by your institution? **Please select one of the following:**

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

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

☐ The IRB reviewed the project as an amendment to an ongoing protocol. Provide justification/rationale why a stand-alone protocol or sub-study was not written for the DoD-funded SOW activities:

☐ Other Institutional review. Describe:

☐ No. The use of specimens/data supported by the DoD/USAMRDC funded project has not been reviewed by my institution because *(explain why):*

Applicability of U.S. Food and Drug Administration (FDA) Requirements. Will data from this protocol be submitted to the FDA (or submitted later to, or held for inspection by, the FDA), as part of an application for a research or marketing permit?

☐ No

☐ Yes. If yes, please note that the FDA and HRPO require prospective IRB review and approval of the research. A regulatory determination of "research not involving human subjects" or "exempt human subjects research" will not suffice.

Study Team. Identify all study team members specific to the DoD-funded research, to include collaborators at other institutions, the team members' affiliated institutions, and their roles and responsibilities.

Study Team Members' Names	Affiliated Institution	Roles and Responsibilities	Funding Status
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.

Conflict of Interest. Do any study personnel have a conflict of interest to declare?

☐ No

☐ Yes. If yes, please explain here.

Data/Specimens. Describe the **number and type** of data/specimens you will use and/or access. Please be specific:

Source of Data/Specimens. Check all that apply. Provide requested details and additional documents as applicable.

Source(s) of Data/Specimens	Source (Colleague's name or institutional entity, e.g., Hospital X Cancer Center Repository, Institution Y Pathology Department, Organization Z Data Repository)	Location(s) (City, State, Country if not U.S.)
☐ Research protocol in which subjects provided informed consent for the collection of their data/specimens. *If checked, include the collection consent form* in your submission for review*		

Source(s) of Data/Specimens	Source (Colleague's name or institutional entity, e.g., Hospital X Cancer Center Repository, Institution Y Pathology Department, Organization Z Data Repository)	Location(s) (City, State, Country if not U.S.)
☐ Repository		
☐ Pathology department		
☐ Colleague(s)		
☐ Surgical discard		
☐ Clinical samples		
☐ Clinical registry		
☐ Commercial vendor		
☐ Post-mortem human specimens (e.g., autopsy, tissue donation program) *If checked, also obtain, complete, and submit the USAMRDC ORP Cadaver Use Submission Form found here: https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/hrpo*		
☐ Publically available source		
☐ Other		

*Does the consent form (clinical or research) used for the collection of the data/specimens include any limitations or prohibitions on future use of data/specimens?

☐ Yes. If yes, explain

☐ No.

Identifiability of Data/Specimens:

Will you/your research team obtain information that directly identifies the original donors of the data/specimens?

☐ No

☐ Yes. If yes, explain

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

☐ No

☐ Yes. If yes, will the key to the code ever be made available to you? ☐ No ☐ Yes. Please explain

Were any study team members involved in the current proposed use of the data/specimens also involved in the original collection of the data/specimens?

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

Use this space to provide any additional pertinent information.