Submission Form for Human Research Protection Official (HRPO) Review

PURPOSE: HRPO review is required by DoDI 3216.02, for research involving humans, human data, or human biospecimens supported by the Department of Defense (DoD).

INSTRUCTIONS: Enter project information in the spaces provided to complete all appropriate sections of the form. Submit this completed form and the study documents to the ARL HRPP office, at usarmy.apg.devcom.mbx.arl-irb-office@army.mil.

NOTE: You cannot initiate the study until you receive HRPO approval.

Section A: Study Information

Study Information	
Principal Investigator Name*:	
Investigator's Institution:	
Study Title:	

*According to the Department of Defense Instruction (DODI) 3216.02, the Principal Investigator (PI) is the individual responsible for the overall conduct of the research study, including ensuring compliance with regulatory requirements, overseeing the safety and welfare of participants, and maintaining the integrity of the research.

Funding Source	
DoD Funding source:	
DoD Program Manager name:	
DoD Program Manager email:	
DoD Contract Officer name:	
DoD Contract Officer email:	
DoD Award number:	

Section B: Institutional Review

The PI's institution is responsible for either a determination or IRB review of projects/protocols/studies involving humans, human biospecimens, or human data.

1) **Is the Project Not Research or Not Human Subjects Research?**	
☐	**Yes (follow instructions below)**
☐	**No (go to question 2)**

For "Not Research" or "Not Human Subjects Research" determinations per 32 CFR 219, submit a copy of the institutional determination/approval, the materials which were reviewed in making this determination, the PI's CV/biosketch, and a copy of the scope of work/proposal. **Skip to Section E.**

2) **Is the Project Exempt from IRB oversight?**	
☐	**Yes**
	If yes, list exemption category(ies): and follow instructions below
☐	**No (go to question 3)**

For "exempt" determinations per 32 CFR 219, submit a copy of institutional determination/approval, the materials which were reviewed in making this determination, a copy of the scope of work/proposal, the PI's CV/biosketch, and human subjects protection training certificate (e.g. CITI certificate). **Skip to Section C, answer questions 1-3, then skip to Section E.**

3) **For IRB Reviewed Projects, complete the following**	
Name of institution providing IRB review:	
Institution's federal wide assurance number:	FWA
Assurance expiration date:	Click here to enter a date.
Name of reviewing IRB:	
IRB approval date:	Click here to enter a date.
IRB expiration date:	Click here to enter a date. or ☐ NA
Method of IRB review (choose below):	
☐ Convened board: ☐ Minimal Risk ☐ Greater than Minimal Risk	
☐ Expedited: List category(ies):	
Method of Documentation of Scientific Review/Merit (select one) ☐ Scientific merit was evaluated during the ARL proposal approval process ☐ IRB approval states that the IRB considered the scientific merit for the study ☐ Institution/IRB SOPs includes a statement regarding consideration of scientific merit (include a copy of the SOP) ☐ Independent scientific review (provide a copy of the review) ☐ Other method (describe and provide documentation):	

IRB APPROVED RESEARCH (Non-exempt): The HRPO reviews and approves the same documents reviewed and approved by the Institutional Review Board (IRB). Submit <u>all</u> IRB submission forms, IRB approved study documents, IRB determinations, a copy of the scope of

work/proposal, PI's CV/biosketch, and human subjects protection training certificate (e.g. CITI certificate). See full checklist in Section D of this form.

Section C: Additional Project Details

1) Study Population Types (select all that apply)		
☐ Normal, healthy adults	☐ Minors	☐ Decisionally impaired
☐ DoD Personnel*	☐ Pregnant women	☐ Non-English Speaking
☐ Prisoners	☐ Employees	☐ Other:
☐ Patient population	☐ Students	

*Prior Command approval is required to recruit DoD personnel for human subjects research. Submit command approval to the HRPO.

2) **Key Study Personnel (**persons who have direct contact with subjects or their identifiable data or specimens.) Add lines as needed.	
Name:	Affiliated Institution:
Study Role/Responsibilities:	
Name:	Affiliated Institution:
Study Role/Responsibilities:	
Name:	Affiliated Institution:
Study Role/Responsibilities:	
Name:	Affiliated Institution:
Study Role/Responsibilities:	

3) International Sites				
☐ Yes	☐ No*	Will the study involve international research sites?		
		a. Will the research be conducted by an established DoD overseas research institution within the host country?	☐ Yes	☐ No
		b. Will the research will be conducted by a DoD overseas institution and include only DoD personnel or U.S. citizens as human subjects.	☐ Yes	☐ No

*If “No” to both a and b, contact the HRPO to discuss additional requirements.

4) Ombudsperson		
☐ Yes*	☐ No	Will the human subject research study recruit DoD personnel in a group setting? If yes*, complete information below:
Name of Ombudsperson(s):		
Institution of Ombudsperson(s):		

5) Conflict of Interest (COI): For definition on COI refer to 32 CFR Part 219		
☐ Yes	☐ No	Does the PI or the Key Study personnel have any COI to declare? ***** If **yes**, explain below:

6) FDA Regulated		
☐ Yes	☐ No	Is this study FDA regulated? If yes, include the following documentation with your submission:
• Products under an IND: Brochure or Informational sheet, Form FDA 1572 for all investigators, any correspondence from U.S. FDA, and IND number. • Products under an IDE review: Device manual and summary of experience with device.		

Section D: Document Checklist for Studies under IRB oversight (Non-exempt)

Use the checklist to organize your HRPO submission package. Provide ALL documents that were submitted to the IRB for review. Please check the box beside each document included with this Submission Form.

☐ Scope of Work/Proposal

☐ PI biosketch

☐ PI human subjects protection training

☐ Research Protocol (provide version number/date:)

☐ IRB Application

☐ IRB Approval Letter(s)
(Original and current approval letter and amendment approval letter – if any)

☐ Informed Consent Document(s) (provide version number/date:)

☐ Assent Forms (provide version number/date:)

☐ HIPAA Authorization (provide version number/date:)

☐ HIPAA Waiver of Authorization (provide version number/date:)

☐ Recruitment Materials (provide version number/date:)

☐ Study Instruments and Data Collection Forms (provide version number/date:)

☐ Scientific Review, if not evaluated during the proposal approval process

☐ Letters of Support/Reliance agreement from collaborating institutions, if applicable

☐ Documentation of Command Support, if applicable

☐ Documentation of Ombudsperson, if applicable

☐ Other (list):

Section E. Reporting Requirements and Responsibilities of the Principal Investigator to the Human Research Protections Official (HRPO).

The Principal Investigator must comply with the following minimum reporting requirements.

Changes to the Protocol: Submit all non-administrative changes to the HRPO approved project. The HRPO must review and accept the IRB's determination when substantive modifications are made to this research protocol before the changes are implemented (see DoDI 3216.02, Section 3.6b). Substantive modifications include, but are not limited to, a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change in study population, significant change in study design, or a change that could potentially increase risks to subjects. All Command Approvals that were obtained to support the project must also be submitted. All other modifications can be implemented prior to approval by the HRPO but must be submitted in a timely manner.

Continuing Review: The HRPO must receive as soon as possible after receipt of approval the investigator's continuing review report to the IRB, documentation of the IRB's review and determination. The HRPO must ensure that appropriate continuing review was undertaken within the required timeframe. In the event there is a lapse in IRB approval, the cease-and-desist document must also accompany the submission to the HRPO.

Study Closure: The HRPO must be informed of the date and reason for study closure (i.e., study completed, insufficient enrollment to sustain the research, etc.). The final study report submitted to the IRB/HRPP, including a copy of any acknowledgement documentation and any supporting documents must be submitted to the HRPO as soon as all documents become available.

Notification: The HRPO must be immediately notified of the occurrence of any of the following (DoDI 3216.02):

- If the IRB used to review and approve the research changes to a different IRB;
- When the institution is notified by any Federal department or agency or national organization that any part of its HRPP is under investigation for cause involving a DoD-supported research protocol;
- UPIRTSOs, suspensions, terminations, and serious or continuing noncompliance regarding DoD-supported research involving human subjects.

Principal Investigator Signature Page. Please sign and submit HRPO package to the ARL HRPP office at usarmy.apg.devcom.mbx.arl-irb-office@army.mil.

I have read and agree to the above reporting requirements and responsibilities of the Principal Investigator to the HRPO.

X	Click here to enter a date.
Principal Investigator Signature	Date

Printed Name: