**U.S. Army Medical Research and Development Command**

**Office of Human and Animal Research Oversight**

**Office of Human Research Oversight**

**DoD IRB Review in Lieu of HRPO Submission Form**

**BACKGROUND:** All United States Army Medical Research and Development Command (USAMRDC) supported research involving human subjects, human data, human specimens, or human cadavers must be reviewed for compliance with Federal, Department of Defense (DoD), and Army human subjects protection requirements and receive approval by the Office of Human and Animal Research Oversight (OHARO) Office of Human Research Oversight (OHRO) prior to implementation.

**PURPOSE:** This form provides the OHARO OHRO with the necessary information to identify all collaborating institutions, performance sites, and involved individuals for a given DoD-supported award/contract and ensure that an appropriate Human Research Protection Official (HRPO) administrative review occurs for all participating institutions in accordance with DoD Instruction 3216.02.

**INSTRUCTIONS:** Use this form **ONLY** when a non-DoD institution(s) relies upon a DoD Institutional Review Board (IRB) for review, approval, and oversight of a collaborative (i.e., cooperative or multi-site) research protocol.

* Enter information in the spaces provided for all applicable fields in Sections A, B, and C of the form.
* Following completion of Sections A, B, and C, *submit the form to the reviewing DoD IRB/Regulatory Office and request they complete Section D*.
* Send the fully completed Submission Form and the supporting documents requested in section B to the electronic mailbox at usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil. An incomplete submission will result in delay in review.

NOTE: If you do not receive an acknowledgement of receipt of your submission within three business days, please send an additional email requesting an update (our firewalls sometimes block receipt of emails with attachments).

For questions or assistance in completing this form, send a message to usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil and a staff member will contact you.

You are reminded not to initiate the study until you receive electronic mail notification from the OHARO OHRO.

**Section A: Protocol Information**.

**1. Protocol Title**:

**2. Associated DoD/USAMRDC Proposal:**

Proposal Log #       Award #       (e.g., W81XWH-01-2-0004)

**3. OHRO Log Number** (if known):

**4. Funded Activities**. Which activities in the protocol are funded by the DoD/USAMRDC?

* 1. [ ]  All protocol activities

 OR

* 1. [ ]  Select activities (Describe in detail):

**5. Point of Contact Regarding this Protocol Submission.**

Study Role:       Contact Information:

**6. Lead POCs at all institutions**. (If more space is needed, insert the cursor in the bottom right cell and use the Tab key to add rows)

Identify lead POCs from ALL participating institutions, consistent with those noted in the approved Statement of Work. Identify collaborators and their affiliated institutions, and provide a brief description of their roles and responsibilities.

| **POCs’ Names** | **Affiliated Institution** | **Roles and Responsibilities** |
| --- | --- | --- |
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**7. Foundations.** Are study personnel employees of any Foundations (e.g., The Geneva Foundation, Henry M. Jackson Foundation, ORISE, Metis Foundation)?

[ ]  No

 [ ]  Yes. If yes, please include the Foundation(s) as an institution in the table in section A.10 below.

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

[ ]  No

 [ ]  Yes. If yes, please explain here.

**9. Involved Institutions and IRB Reviews**. List **ALL** institution(s) involved in this protocol and the study activities occurring at each institution (Columns A and B). If employees of the institution will interact with subjects or have access to identifiable data, complete the rest of the columns (C-J) for each institution. Identify all reviewing IRBs and the IRB actions taken regarding this protocol. If more rows are needed, attach additional page(s) to the end of the submission form.

| Institution *(If multi-site, include each site)* | Study Activities*(e.g. recruitment, enrollment, data/specimen collection, analysis, data storage)* | DHHS Federalwide Assurance #([Click here to search](http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc)) or DoD Assurance # | \*Name of DoD IRB | IRB Approval Status | IRB Approval Date | IRB Approval Expiration Date | Type of IRB Review | IRB Determin-ation |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|       |       |       |       | Choose an item. | Click here to enter a date. | Click here to enter a date. | Choose an item. | Choose an item. |
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\*Single IRB Requirement: For institutions located in the U.S. engaged in multi-site cooperative research conducted in the U.S., a single IRB must review for all sites. Provide the name of the DoD IRB reviewing for all sites in the table.

**10. Use of Medical Products**.

 a. Drugs, Biologics or Dietary Supplements. Does the protocol assess the use a drug, biologic or dietary supplement?

[ ]  Yes (If Yes, continue to question (1))

[ ]  No (If No, skip to question b.)

 (1) Is the purpose of the protocol to determine the safety or efficacy of the drug, biologic, or dietary supplement?

[ ]  Yes (If Yes, complete the table below.)

[ ]  No (If No, skip to question b.)

 (2) Does the protocol assess the use of a drug, biologic or dietary supplement that is FDA approved AND will be used in accordance with the labeling and indications as reviewed by the FDA?

[ ]  Yes (If Yes, protocol may be exempt from an Investigational New Drug (IND) application, continue to the table below.)

[ ]  No (If No, continue to the table below.)

|  |  |  |  |
| --- | --- | --- | --- |
| Product Name(s) | Has the IRB/Institution or FDA evaluated whether an IND is required? *(Yes/No)* | IND Application Status *(Indicate IND#, IND pending, or IND exempt)* | Who holds the IND? |
|       |       |       | [ ]  Sponsor\*[ ]  Investigator[ ]  Other:       |
|       |       |       | [ ]  Sponsor\*[ ]  Investigator[ ]  Other:       |
|       |       |       | [ ]  Sponsor\*[ ]  Investigator[ ]  Other:       |

\*Include documentation from the sponsor or FDA identifying the IND number for this study.

 b. Investigational Medical Devices.

 (1) Is the purpose of the protocol to evaluate the safety or effectiveness of a medical device (to include decision support software, mobile medical applications, *in vitro* diagnostic (IVD) devices and assays with IVD devices) as defined at 21 CFR 812?

[ ]  Yes (If Yes, continue to next question.)

[ ]  No (If No, skip to Section B, Checklist of Documents to be Submitted to OHARO OHRO.)

 (2) 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?

[ ]  Yes (If Yes, complete the table below.)

[ ]  No (If No, skip to Section B, Checklist of Documents to be Submitted to OHARO OHRO.)

|  |  |  |  |
| --- | --- | --- | --- |
| Device Name(s)/Manufacturer | Has the IRB/Institution or FDA evaluated whether an IDE is required? *(Yes/No)* | IDE status\* *(Indicate not applicable, pending, IDE#, or IDE exempt)* | Who holds the IDE? |
|       |       |       | [ ]  Sponsor\*[ ]  Investigator\*[ ]  Other:       |
|       |       |       | [ ]  Sponsor\*[ ]  Investigator\*[ ]  Other:       |
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| \*Sponsor/PI’s Device Risk Determination for Device(s) as Used in this Study |
| [ ]  Non-Significant Risk **Note:** Study is subject to abbreviated IDE requirements. Provide documentation of a Non-Significant Risk determination reviewed by the convened IRB.[ ]  Significant Risk Device **Note:** Study must have an FDA-approved IDE.[ ]  Study is Exempt from IDE requirements. |

 (3) Does the protocol use a medical device that is FDA cleared AND will the device be used in accordance with the labeling and indications as reviewed by the FDA?

[ ]  Yes

 [ ]  No

**Section B. Checklist of Documents to be Submitted to the OHARO OHRO**

**PI Name**:

**Protocol Title**:

**1. In addition to this completed and signed Submission Form, please provide the following:**

[ ]  IRB-approved Research Protocol. (Please note the version(s) and date(s) of the approved protocol:      .)

[ ]  IRB Application *(If required by the reviewing IRB).* (Indicate the version(s) and date(s) of the IRB Application:      .)

[ ]  IRB Approval Letter(s)

[ ]  Completed and signed reviewing IRB/IRB Office confirmation page from Section D of this submission form

[ ]  Copies of determinations from non-engaged collaborators, if applicable. See Section D.3 below

**2. International Sites**. If your study involves international research sites, please contact the OHARO OHRO for guidance on completing an international protocol submission form and requirements for international research sites. The site-specific protocol addendum form is found on the OHRO website: [Click Here](https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo)

**3. Cadaver Research.** Activities involving human cadavers, to include cadaveric specimens, supported by the USAMRDC must be reviewed for compliance with the U.S. Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation (RDT&E), Education, or Training, and approved by the OHARO. If your research involves use of human cadavers, please complete the Cadaver Submission Form found on the OHRO website: [Click Here](https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo)

**Section C. Reporting Requirements and Responsibilities of the Principal Investigator to the USAMRDC OHARO OHRO.**

The Principal Investigator must comply with the following minimum reporting requirements. Specific reporting requirements for the protocol will be included in the OHRO Approval Memorandum. Failure to comply could result in suspension of funding.

1. The Principal Investigator/awardee institution must notify this office in the event of initiation of a sub-contract or other agreement with another non-DoD institution for performance of the proposed research. The OHARO OHRO will review the new or amended research in accordance with applicable DoD requirements.

2. The Principal Investigator must promptly report the following study events for any research site to the OHARO OHRO by telephone (301-619-2165), by email (usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil), or by facsimile (301-619-7803):

 (a) All unanticipated problems involving risk to subjects or others.

 (b) Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the sponsor, or regulatory agencies.

 (c) Any instances of serious or continuing noncompliance with the federal regulations or IRB requirements.

 (d) The knowledge of any pending compliance inspection/visit by the Food and Drug Administration (FDA), Office for Human Research Protections, or other government agency concerning this clinical investigation or research.

 (e) The issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any government regulatory agencies.

 (f) Any changes of the IRB used to review and approve the research.

**Section D. DoD IRB Confirmation of Review and Oversight of Non-DoD Performance Sites**

Per the 15 April 2020 DoD Instruction (DoDI) 3216.02, when a DoD IRB serves as the reviewing IRB, the DoD IRB approval will constitute Human Research Protection Official review; an additional Human Research Protection Official review is not required. The research described above has received funding from U.S. Army Medical Research and Development Command (USAMRDC) (or other DoD funding source), and therefore must receive written notification by the Office of Human and Animal Research Oversight (OHARO) Office of Human Research Oversight (OHRO) prior to implementation. Upon receipt and assessment of the information and documents requested in this submission form, the OHARO OHRO will issue a memorandum indicating that the DoDI’s requirements for Human Research Protection Official review and approval have been met. Please call the OHARO OHRO at 301-619-7550 if you have questions.

1. The       (DoD IRB name) IRB has reviewed and approved the above-described research for all **engaged** performance sites as detailed in the table in Section A.6 of this form.

[ ]  Yes

 [ ]  No

 [ ]  Pending approval

2. Indicate whether employees of Foundations listed in section A.7 or A.10 above are conducting the research under the DOD institution’s assurance or the Foundation’s assurance.

 [ ]  DOD Assurance

 [ ]  Foundation Assurance

 [ ]  Other (e.g., Individual Investigator Agreement) Explain

 [ ]  N/A, no Foundation employees involved in this research study.

3. The IRB/IRB Office has reviewed for, or has secured/received determinations for, all **non-engaged non-DoD sites** as listed in the table in Section A.6 of this form.

[ ]  Yes (ensure the PI submits copies of the determinations to OHARO OHRO with other required documents listed in Section B of this form)

 [ ]  No

 [ ]  N/A (there are no non-engaged non-DoD sites)

4. Please confirm that the       (name of the organization operating the DoD IRB) has entered into a written agreement with all non-DoD institution(s) relying on the DoD IRB as detailed in the table in Section A.6 of this form. *(When IRB oversight is conducted by an IRB that is not operated by the institution engaged in the research, the institution and the organization operating the IRB must document the institution’s reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the regulatory requirements (e.g., via an Institutional Agreement for IRB Review) [32 CFR 219.103(e)]).*

[ ]  Yes

 [ ]  No Explain

5. Please provide the IRB’s DHHS Office for Human Research Protections Registration Number:

IRB

**IRB Representative Signature Page.** Please sign electronically or sign and scan this signature page. Return the completed and signed form to the Principal Investigator.

**I confirm the information provided in Section D above.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click here to enter a date.

Signature

Printed Name:

Title:

Phone number and email address: