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

**Office of Human and Animal Research Oversight**

**Office of Human Research Oversight**

**Human Research Protocol Submission Form**

**Administrative Review of Extramural\* Research**

**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 and Department of Defense (DoD) human subjects protection requirements and receive approval by the Office of Human and Animal Research Oversight Office of Human Research Oversight (OHRO) prior to implementation.

**INSTRUCTIONS:** Enter the requested information in the spaces provided to complete all applicable sections of the form. An incomplete submission may result in delay in review.

This form has three sections: Section A requests protocol information; Section B includes a checklist of documents for submission to the OHRO; and Section C lists the reporting requirements and responsibilities of the Principal Investigator to the OHRO.

Complete a Protocol Submission Form for each human subjects research protocol performed under the DoD/USAMRDC-funded proposal. For example, if your research proposal includes three separate research protocols, submit one completed Protocol Submission Form for each protocol.

The research protocol submitted for OHRO review **must only include those activities funded by the DoD**, as referenced in the approved Statement of Work (SOW). The OHRO will not review protocols submitted for DoD-funded activities if such studies have been added to an ongoing/existing protocol.

For multi-site studies, please complete this form for the Master Protocol only at this time. Identify all known sites participating in the protocol. Additional site-specific documents will be requested at a later date. If additional sites are added at a future time, submit a new Protocol Submission Form for the additional site(s).

Effective 20 January 2020, any institution located in the U.S. that is engaged in multi-site cooperative research must rely upon approval by a single Institutional Review Board (IRB) for that portion of the research that is conducted in the U.S. (section .114 of the Common Rule). Please identify the designated single IRB for all sites in the table in section A.7 below.

Please submit this completed form and all required documents via the **Electronic Biomedical Research Application** **Portal (eBRAP)** ([ebrap.org](https://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 section B of 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, consent form, IRB approval.

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 OHRO Research Administrative Support point of contact or to usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil requesting an update and receipt confirmation.

For questions regarding OHRO human research protocol review requirements or assistance in completing this form, email your assigned OHRO Research Administrative Support point of contact or usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil or leave a message at 301-619-2165 and a staff member will contact you.

You are reminded not to initiate the study until you receive approval from the OHRO.

**NOTE:** If your protocol meets the criteria for secondary research involving the use of data/specimens, please see “Guidance on OHRO Review Requirements for Research Involving the Secondary Use of Data/Specimens,” and complete the OHRO Submission Form – Secondary Research Involving the Use of Data/Specimens available on the OHRO website https://mrdc.health.mil/index.cfm/collaborate/research\_protections/hrpo.

*\*The OHRO defines intramural research as research conducted by USAMRDC laboratories. All other USAMRDC-managed research is considered extramural.*

**Section A: Protocol Information**. The purpose of this section is to obtain administrative details for each protocol submitted to OHRO. The information is required for the OHRO to review and approve each research protocol and performance/collaborative site(s) associated with the study.

**1. Protocol Title**:

**2. Funding**

 a. Associated DoD/USAMRDC Proposal:

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

 b. Is there another DoD award/funding source supporting this project?

 [ ]  No

 [ ]  Yes. If yes, please explain

 c. Is there a **non-**DoD award/funding source supporting this project?

 [ ]  No

 [ ]  Yes. If yes, please explain

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

**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):

**NOTE: The protocol submitted for OHRO review must include only those activities funded by the DoD, as referenced in the SOW. If the DoD funded activities have been added to an ongoing/existing protocol, the OHRO requires the drafting and IRB approval of a stand-alone protocol that details only the activities funded by the DoD.**

**5. Protocol.**

 a. Will/has the submitted protocol also be used for other DoD-funded research (e.g., the protocol is linked to two different awards)?

 [ ]  No

 [ ]  Yes. If yes, please explain

 b. The IRB reviewed the protocol as a(n):

 [ ]  New, standalone protocol.

 OR

 [ ]  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:

**6. Key Study Personnel**. (If more space is needed, attach additional page(s) to the end of this form)

 a. List all key study personnel below, including the Principal Investigator (PI) and other study team members, along with a brief statement of their study role(s) and responsibilities. Note: Key study personnel are persons who have direct contact with subjects or their identifiable data or specimens.

| **Key Personnel Name** (include degrees and credentials) | **Affiliated Institution** | **Roles and Responsibilities** | **Funding Status** |
| --- | --- | --- | --- |
|       |       | Study Role(s):      Responsibilities:       | Choose an item. |
|       |       | Study Role(s):      Responsibilities:       | Choose an item. |
|       |       | Study Role(s):      Responsibilities:       | Choose an item. |
|       |       | Study Role(s):      Responsibilities:       | Choose an item. |
|       |       | Study Role(s):      Responsibilities:       | Choose an item. |
|       |       | Study Role(s):      Responsibilities:       | Choose an item. |
|       |       | Study Role(s):      Responsibilities:       | Choose an item. |
|       |       | Study Role(s):      Responsibilities:       | Choose an item. |
|       |       | Study Role(s):      Responsibilities:       | Choose an item. |
|       |       | Study Role(s):      Responsibilities:       | Choose an item. |

 b. List all other personnel involved in the research (e.g., statistician, consultants, collaborators).

| Other Involved Personnel | Study Roles and Responsibilities |
| --- | --- |
| Name:      Affiliated Institution:       | Study Role(s):      Responsibilities:       |
| Name:      Affiliated Institution:       | Study Role(s):      Responsibilities:       |
| Name:      Affiliated Institution:       | Study Role(s):      Responsibilities:       |
| Name:      Affiliated Institution:        | Study Role(s):      Responsibilities:       |
| Name:      Affiliated Institution:        | Study Role(s):      Responsibilities:       |

 c. Conflict of Interest. Do any study personnel have a conflict of interest (COI) to declare?

 [ ]  No

 [ ]  Yes. If yes, please explain and state whether there is an approved COI management plan in place.

 d. Points of contact (POC). Please contact information for:

 Primary POC: Click or tap here to enter text.

 POC for multi-site submissions: Click or tap here to enter text.

 Lead site for multi-site studies: Click or tap here to enter text.

**7. Institution(s) and IRB(s**) (*Note: to add rows to the tables, place cursor in bottom right cell and hit tab*)

 a. Identify all known participating sites and site Principal Investigators involved in this protocol and the study activities occurring at each institution. If employees of the institution will interact with subjects or have access to identifiable data, provide the institution’s DHHS Federalwide Assurance (FWA) number. For Multi-Site Studies: additional site documents will be requested at a later date. If additional sites are added at a future time, submit a new Protocol Submission Form for the additional site(s).

| Institution | Principal Investigator(last name) | Study Activities*(e.g., recruitment, enrollment, data/specimen collection, analysis, data storage, data center)* | FWA #([Click here to search](http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc)) |
| --- | --- | --- | --- |
|       |       |       |       |
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 b. Identify all reviewing IRBs and the IRB actions taken regarding this protocol.\*

| Name of Reviewing IRB | IRB Approval  | IRB Approval Date | IRB Approval Expiration Date | Type of IRB Review | IRB Determination | \*\*IRB ApprovedWaivers*(Indicate: A, B, C, D)* |
| --- | --- | --- | --- | --- | --- | --- |
|       | Choose an item. | Click here to enter a date. | Click here to enter a date. | Choose an item. | Choose an item. |       |
|       | Choose an item. | Click here to enter a date. | Click here to enter a date. | Choose an item. | Choose an item. |       |

\*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 designated IRB reviewing for all sites in the table. For international research sites, include reviewing Ethics Committee(s).

\*\*IRB Approved Waivers: In the space provided, type the letter(s) representing the waivers granted by the IRB, if applicable: **A**. Waiver or alteration of the requirement to obtain informed consent from subjects; **B**. Waiver of the requirement to obtain a signed consent form from subjects; **C**. Waiver of HIPAA Authorization requirements for this protocol; **D**. Waiver of HIPAA Authorization requirements for recruitment purposes only.

**8. Use of Medical Products**.

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

[ ]  No

 a. Drugs, Biologics or Dietary Supplements. Does the protocol include the use of any drugs (to include contrast agents, radiotracers, etc.), biologics, or dietary supplements?

[ ]  Yes – If Yes, continue to question 1.

[ ]  No – If No, skip to question b.

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

[ ]  Yes – If Yes, complete the table below.

[ ]  No – If no, briefly explain the use of the drug, biologic, or dietary supplement in this protocol and continue to question 2. Click or tap here to enter text.

 (2) Is the use of the drug, biologic, or dietary supplement in accordance with its FDA approval AND will it 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) and IND Number (if applicable) | Has the IRB/Institution or FDA evaluated whether an IND is required? | IND Application Status | Who holds the IND? |
|       | Choose an item. | Choose an item. | [ ]  Sponsor\*[ ]  Investigator[ ]  Other:       |
|       | Choose an item. | Choose an item. | [ ]  Sponsor\*[ ]  Investigator[ ]  Other:       |
|       | Choose an item. | Choose an item. | [ ]  Sponsor\*[ ]  Investigator[ ]  Other:       |

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

 b. Investigational Medical Devices.

***Medical Device Definition:*** *An instrument, apparatus (****to include software and algorithms****), implement, machine, contrivance, implant, in vitro reagent…or component, part, or accessory…intended to diagnose a disease or condition or to cure, mitigate, treat, or for prevention of disease or it affects the structure or function of the body…and does not achieve its primary purpose through chemical action…or by being metabolized.*

 (1) Does the protocol include the use of a medical device(s) as defined above?

[ ]  No (If no, go to Section B)

[ ]  Yes. Answer the next two questions:

(a) Is the medical device FDA cleared AND will the device be used in accordance with the labeling and indications as reviewed by the FDA?

[ ]  Yes

[ ]  No

(b) Is the purpose of your protocol to evaluate the effectiveness or safety of the medical device (to include decision support software, mobile medical applications, *in vitro* diagnostic (IVD) devices and assays with IVD devices)?

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

[ ]  No (go to Section B)

|  |  |  |  |
| --- | --- | --- | --- |
| [ ] Device Name(s)/Manufacturer | Has the IRB/Institution or FDA evaluated whether an IDE is required? *(Yes/No)* | IDE status\* | Who holds the IDE (if applicable)? |
|       | Choose an item. | Choose an item. | [ ]  Sponsor\*[ ]  Investigator\*[ ]  Other:       |
|       | Choose an item. | Choose an item. | [ ]  Sponsor\*[ ]  Investigator\*[ ]  Other:       |
|       | Choose an item. | Choose an item. | [ ]  Sponsor\*[ ]  Investigator\*[ ]  Other:       |
| \*Sponsor’s/PI’s/FDA’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. |

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

**1. IRB-Approved/Required Documents**. Please provide the documents listed below. These are the core required documents for acceptance of the protocol submission for OHRO review. Please check the box beside each document included with this Protocol Submission Form.

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

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

[ ]  IRB-approved informed consent document(s), HIPAA Authorization forms, and assent forms (if applicable). (Please note the version(s) and date(s) of the approved informed consent document(s) here:      .)

[ ]  IRB approval letter(s) (Original/initial approval and current approval letter and amendment approval letter (if any))

**2. Other applicable and available study documents**. When available, submit the following research-related documents for OHRO review (if applicable). Please check the box beside each document included with this Protocol Submission Form.

[ ]  Documentation of human subjects training for the Principal Investigator, Co-Investigator(s), Associate Investigator(s) (**REQUIRED**)

[ ]  Subject recruitment material (e.g., telephone recruitment script, online or print advertising)

[ ]  Survey instruments

[ ]  Unit Commander letter of support (if military populations involved)

[ ]  Other documents signed by the subject (e.g., procedural consent, consent for sample donation, consent for testing for communicable diseases, audio/video release form)

[ ]  FDA determination/communication related to IND/IDE

[ ]  Investigator’s Brochure/medical product package insert

[ ]  Device manual

[ ]  Form FDA 1572

**3. International Sites**. If your study involves international research sites, please contact the 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)

**4. Multi-Site Protocols**. If this is a multi-site protocol, you will be asked to provide each site’s IRB approved documents (including the IRB Application) as a separate submission for OHRO review. If the IRB application is unavailable for a site, complete the Site-Specific Protocol Addendum found on the OHRO website: [Click Here](https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo).

**5. 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 Office of Human and Animal Research Oversight (OHARO). If your research involves use of human cadavers or cadaveric materials (to include post-mortem specimens), please complete the OHARO 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 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. Substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the OHRO for approval prior to implementation. The USAMRDC OHRO defines a substantive modification as a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc.), significant change in study design (i.e., would prompt additional scientific review) or a change that could potentially increase risks to subjects.

2. Any changes of the IRB used to review and approve the research will be promptly reported to the OHRO.

3. All unanticipated problems involving risk to subjects or others must be promptly reported by telephone (301-619-2165), by email (usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil), or by facsimile (301-619-7803) to the OHRO. A complete written report will follow the initial notification. In addition to the methods above, the complete report can be sent to the U.S. Army Medical Research and Development Command, ATTN: FCMR-RP, 810 Schreider Street, Fort Detrick, Maryland 21702-5000.

4. Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the Sponsor, or regulatory agencies will be promptly reported to the OHRO.

5. A copy of the continuing review approval notification by the reviewing IRB, if required, must be submitted to the OHRO as soon as possible after receipt. Please note that the OHRO may also conduct audits at the time of continuing review. Additional information and documentation may be requested at that time.

6. The final study report, including any acknowledgement documentation and supporting documents, must be submitted to the OHRO when available.

7. The knowledge of any pending compliance inspection/visit by the FDA, DHHS Office of Human Research Protections (OHRP), or other government agency concerning this research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any regulatory agencies including legal or medical actions and any instances of serious or continuing noncompliance with the regulations or requirements, must be promptly reported to the OHRO.

**Principal Investigator Signature Page.** Please sign electronically or sign and scan this signature page.

**I have read the above reporting requirements and responsibilities of the Principal Investigator to the OHRO. The protocol will not be initiated until written notification of approval of the research project is issued by the OHRO.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol Principal Investigator Signature Date: Click here to enter a date.

Printed Name:

Point of contact regarding this protocol submission:

Study Role:       Contact Information: