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

**Office of Research Protections**

**Human Research Protocol Submission Form**

**Administrative Review of Extramural\* Research**

**PURPOSE:** 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 Research Protections (ORP) Human Research Protection Office (HRPO) prior to implementation.

**INSTRUCTIONS:** Enter protocol information in the spaces provided to complete all applicable sections of the form. Submit this completed form and the protocol documents to the electronic mailbox at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.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 and receipt confirmation (DoD server firewalls sometimes block receipt of emails with attachments).

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

Complete a Protocol Submission Form for each human subjects research protocol performed under the DoD/USAMRDC 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 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 multi-site studies, please complete this form for the Master Protocol only at this time. Identify all known participating sites 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).

Note that 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 6 below.

For questions regarding ORP HRPO human research protocol 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.

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

*\*The ORP HRPO 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 ORP HRPO. The information is required for the ORP HRPO to review and approve each research protocol and performance and collaborative site(s) associated with the study.

**1. Protocol Title**:

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

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

**3. HRPO Log Number** (if known): A-

**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 HRPO 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 HRPO requires the drafting of a stand-alone protocol that details only the activities funded by the DoD.**

**5. 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 Study Personnel (Include Degrees and Credentials) | Study Roles and Responsibilities | Primary Point of Contact (Select one) |
| 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:       | [ ]  |
| Name:      Affiliated Institution:       | Study Role(s):      Responsibilities:       | [ ]  |

 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 to declare?[ ]  No

 [ ]  Yes. If yes, please explain here.

| 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. If you need assistance, please contact your local IRB office or the ORP HRPO at 301-619-2165 or usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil. |
| --- |
| A | B | C | D | E | F | G | H | I | J |
| Institution *(If multi-site, include each site and site PI)* | 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)) | \*Name of Reviewing IRB | \*\*IRB Approval *(Indicate: Yes, No, Pending)* | IRB Approval Date | IRB Approval Expiration Date | Type of IRB Review*(Full Board or Expedited)* | IRB Determin-ation | \*\*\*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. |       |
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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 designated IRB reviewing for all sites in the table.

\*\*IRB Approval: Indicate whether IRB approval has taken place or is pending. If there are any Institutional Agreements for IRB review planned, describe in the space provided.

IRB Determination: Indicate the determination made by the IRB during the initial review of the protocol. Please contact your IRB office for assistance.

\*\*\*IRB Approved Waivers: In the space provided, type the letter(s) representing the waivers granted by the IRB: **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.

Multi-Site Studies: Identify all known participating sites, site Principal Investigators, and IRBs in the above table. 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).

**7. 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 i.)

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

 i. 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, skip to question b)

 ii. 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 your 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 ORP)

 (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 ORP)

|  |  |  |  |
| --- | --- | --- | --- |
| 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:       |
|       |       |       | [ ]  Sponsor\*[ ]  Investigator\*[ ]  Other:       |
| \*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 ORP**

**PI Name**:

**Protocol Title**:

The ORP reviews and approves the same documents reviewed and approved by the local Institutional Review Board (IRB). To promote a timely review, submit all IRB-approved study documents, additional applicable documents, and this Protocol Submission Form.

If your protocol meets the criteria for Secondary Research Involving the Use of Data/Specimens please complete the HRPO Submission Form – Secondary Research Involving the Use of Data/Specimens found on the ORP HRPO website https://mrdc.amedd.army.mil/index.cfm/collaborate/research\_protections/hrpo and submit your institution’s exemption determination letter. Contact the ORP HRPO for protocol submission instructions at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil or 301-619-2165.

**1. Institutional Review Board (IRB)-Approved Documents**. Please provide all documents that were submitted to the IRB for review. These are required documents for acceptance of the protocol submission for ORP review. Please check the box beside each document included with this Protocol Submission Form.

[ ]  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:      .)

[ ]  Informed Consent Document(s), HIPAA Authorization Forms, and Assent Forms. (Please note the version(s) and date(s) of the approved informed consent document(s) here:      .)

[ ]  IRB Approval Letter(s) (Original and current approval letter and amendment approval letter (if any))

**2. Other applicable and available study documents**. If applicable and when available, submit the following research-related documents for ORP review. Please check the box beside each document included with this Protocol Submission Form.

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

[ ]  Scientific/Peer Review of Protocol

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

[ ]  Study instruments and data collection forms

[ ]  Conflict of Interest forms (per your institutional requirements)

[ ]  Additional committee and regulatory committee approvals (e.g., radiation control committee, institutional biosafety committee, etc.)

[ ]  Letter of Support from collaborating institutions

[ ]  Unit Commander Letter of Support (if military sites 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 related to IND/IDE

[ ]  Medical Product Package Insert/ Investigational Brochure

[ ]  Device Manual

[ ]  Form FDA 1572

[ ]  Case Report Forms

**3. International Sites**. If your study involves international research sites, please contact the ORP HRPO 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 HRPO website: [Click Here](https://mrmc.amedd.army.mil/index.cfm?pageid=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 ORP HRPO review. If the IRB application is unavailable for a site, complete the Site-Specific Protocol Addendum found on the HRPO website: [Click Here](https://mrmc.amedd.army.mil/index.cfm?pageid=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 ORP. If your research involves use of human cadavers, please complete the ORP Cadaver Submission Form found on the HRPO website: [Click Here](https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo)

**Section C. Reporting Requirements and Responsibilities of the Principal Investigator to the USAMRDC ORP Human Research Protections Office (HRPO).**

The Principal Investigator must comply with the following minimum reporting requirements. Specific reporting requirements for the protocol will be included in the HRPO 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 HRPO for approval prior to implementation. The USAMRDC ORP HRPO 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 USAMRDC ORP HRPO.

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@mail.mil), or by facsimile (301-619-7803) to the HRPO. A complete written report will follow the initial notification. In addition to the methods above, the complete report can be sent to the US 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 USAMRDC ORP HRPO.

5. A copy of the continuing review approval notification by the IRB of Record, if required, must be submitted to the HRPO as soon as possible after receipt. Please note that the HRPO also conducts 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 HRPO 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 HRPO.

**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 USAMRDC ORP HRPO. The protocol will not be initiated until written notification of approval of the research project is issued by the USAMRDC ORP HRPO.**

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

Printed Name:

Point of Contact Regarding this Protocol Submission:

Study Role:       Contact Information: