**Army Human Research Protections Office**

**Office of the Surgeon General**

**Protocol Submission Form for Human Research Protection Official (HRPO) Review Required by DFARS Clause**

PURPOSE: HRPO review is required by DoDI 3216.02, Encl 3 4.c. for research supported by the Department of Defense (DoD), is conducted by non-DoD institutions, for the purpose of ensuring compliance with DoD requirements for the protection of human subjects involved in research. This is a life-cycle review, which begins as a pre-requisite for research involving human subjects to begin, and continues through the course of the study until it is closed. On behalf of the Department of the Army, HRPO review is provided by the Army Human Research Protections Office (AHRPO) or designee.

INSTRUCTIONS: Enter protocol 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.ccdc.mbx.arl-irb-office@mail.mil. An incomplete submission will results in delay in review, which will often include sending the form back to the government POC. This form is divided into three sections: Section A requests protocol information; Section B is a checklist of documents to be submitted to the HRPO, and Section C lists the reporting requirements and responsibilities of the Principal Investigator to the HRPO.

NOTE: Complete a Protocol Submission Form for each human subjects research protocol. For example, if your research proposal includes three separate research protocols, submit one completed Protocol Submission Form for each protocol.

For multi-site studies, please complete this form for the Master Protocol only at this time. Identify all participating sites in the protocol in the Involved Institutions and Institutional Review Board (IRB) Reviews table.

NOTE: You are reminded not to initiate the study until you receive HRPO approval.

**Section A: Study Information**

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| **Study Information** |
| Principal Investigator Name: |  |
| Study Title: |  |
| Investigator’s Institution: |  |

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| **Funding Source** |
| Identify DoD Funding source:  |  |
| Contract Officer: |  |
| Contract Officer Contact Information:  |  |
| Award number:  |  |

3.

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| **Research Involving Human Subjects determinations** |
| [ ]  Yes**\*** [ ]  No | Is this activity "research involving human subjects"?  |
| **\*** Ifyes, is this activity "exempt" from IRB review IAW 32 CFR 219.101(b)? | [ ]  Yes**\*** [ ]  No**\*\*** |
|  | **\*** If Yes, list exempt category(ies) (include subcategories)? |  |
| **\*\*** If No, complete the items below: |  |
| Name of institution providing IRB review: |
| Institution's federal assurance number: |
| Assurance expiration date: Click here to enter a date. |
| Name of reviewing IRB: |
| Contact person at the IRB:  |
| IRB approval date: Click here to enter a date. |
| IRB expiration date: Click here to enter a date. |
|  |
| Method of IRB review: [ ]  Convened board [ ]  Expedited **\*** |
|  | **\*** If **expedited,** list category(ies): |  |

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| **IRB risk level determination** |
| [ ]  Yes**\*** [ ]  No | **Research Monitor:** Is the studyhuman subject research that requires a Research Monitor?*(****required for greater than minimal risk studies****)***\*** If yes**,** complete information below: |
|  | Name:  |
| Affiliated Institution: |
| When and how was the monitor notified of his/her responsibilities: |
|  |
| [ ]  Yes**\*** [ ]  No | **Ombudsman:** Is the studyhuman subject research that will recruit military personnel in a group setting?**\*** Ifyes, complete information below: |
|  | Name: |
| Affiliated Institution: |
| When and how was the ombudsman notified of his/her responsibilities: |

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| **Scientific Review** |
| [ ]  Yes**\*** [ ]  No | Was scientific review considered by the IRB (DoDI 3216.02, Enc 3.4.b(2))? **REQUIRED for all non-exempt (IRB reviewed) studies.****\*** If yes, describe the scientific review process and how this was considered by the IRB below: |
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| **International Sites** |
| [ ]  Yes**\*** [ ] No | Will the study involve international research sites? \*If yes, answer a. and b. below: |
|  | **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 |

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| **Research Personnel and Support.** (If more space is needed, attach additional page(s) to the end of this form) |
| Identify all **key study personnel** below, excluding the Principal Investigator (PI) who has been listed above. Note: Key study personnel are persons who have direct contact with subjects or their identifiable data or specimens. |
| [ ]  Yes [ ]  No |  Are any non-Army people involved?  |
| **Key Study Personnel** |
| 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:  |

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| **Conflict of Interest (COI):** For definition on COI refer to 32 CFR Part 219 and Army Regulation 70-25  |
| [ ]  Yes**\*** [ ] No | Is/Are there any conflict(s) of interest to declare?**\*** If **yes**, explain below: |
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9.

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| **Identify all institutions involved in or supporting this research** |
| Name and location of institution | Activities undertaken by this institution on behalf of this research |
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| **Study Population Types** |
| [ ]  Normal, healthy adults | [ ]  Children  | [ ]  Decisionally impaired |
| [ ]  Employees | [ ]  Military  | [ ]  Pregnant women/fetuses |
| [ ]  Prisoners | [ ]  DoD Civilian | [ ]  Non English Speaking |
| [ ]  Patient population | [ ]  Students  | [ ]  Other:  |

11.

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| **FDA Regulated** |
| [ ]  Yes [ ]  No  | Is this study FDA regulated?  |

12.

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| **Multi-site Studies**Complete for this section for multi-site only where applicant is the lead institution |
| A | B | D | E | F | G | H | I | J |
| Institution Name  | Study Activities at that Institution*(e.g. recruitment, enrollment, data/specimen collection, analysis, data storage)* | 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)* | Study Risk Level Determination made by IRB | IRB Regulatory determinations: Waivers, Subpart Findings, HIPAA findings, Device findings, etc |
|  |  |  |  | Click here to enter a date. | Click here to enter a date. |  | Choose an item. |  |
|  |  |  |  | Click here to enter a date. | Click here to enter a date. |  | Choose an item. |  |
|  |  |  |  | Click here to enter a date. | Click here to enter a date. |  | Choose an item. |  |

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

NOT HUMAN SUBJECT RESEARCH:

If this study has been determined to not meet the definition of “research involving human subjects” per 32 CFR 219, please submit a copy of the not-human-subject research-determination and the materials which were reviewed in making this determination.

EXEMPT RESEARCH:

If the study has been determined to be “exempt” from 32 CFR 219, please submit a copy of the materials which were reviewed in making this determination and the determination letter.

IRB APPROVED RESEARCH (Non-exempt):

The HRPO reviews and approves the same documents reviewed and approved by the Institutional Review Board (IRB). Submit all IRB submission forms, IRB approved study documents, IRB determinations and this Submission Form. See checklist below

**1. Institutional Review Board (IRB)-Approved Documents**. Provide all documents that were submitted to the IRB for review. Please check the box beside each document included with this Protocol Submission Form.

[ ]  Research Protocol (provide version number/date:)

[ ]  IRB Application

[ ]  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 (or indication that IRB considered scientific merit)

[ ]  Letters of Support from collaborating institutions

[ ]  Documentation of Command Support

[ ]  Other (list):

**2. IRB Approvals**

[ ]  IRB Approval Letter(s)

 (Original and current approval letter and amendment approval letter – if any)

**Section C. 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. Specific reporting requirements for the protocol will be included in the HRPO Approval Memorandum.

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

**Substantive Changes to the Protocol:** The HRPO must review and accept the IRB’s determination when substantive modifications are made to this research protocol, and any modifications that could potentially increase risk to subjects, before the changes are implemented. Substantive modifications include 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.

**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, and all Command Approvals that were obtained to support the research. 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. Please note that the HRPO can conduct random audits at the time of continuing review and additional information and documentation may be requested.

**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, 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, Encl 3 4.b(4)):

* 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.rdecom.mbx.arl-irb-office@mail,mil.

**I have read 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:

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| Point of Contact Regarding this Study Submission |  |
| Study Role |  |
| Contact Information |  |