US Special Operations Command
Human Research Protection Office

Human Research Protocol Submission Form for Headquarters Level Administrative Review of Extramural* Research

PURPOSE: All United States Special Operations Command (USSOCOM) supported research involving humans, human data, human specimens, or cadavers must be reviewed for compliance with Federal and Department of Defense (DoD) human subjects protection requirements and approved by the Human Research Protection Office (HRPO).

INSTRUCTIONS: Enter protocol information in the spaces provided to complete all appropriate sections of the form. Submit this completed form and the protocol documents to the electronic mailbox at hrpp@socom.mil. An incomplete submission will result in delay in review. 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 USSOCOM Human Research Protection Office (HRPO).

NOTE: Complete a Protocol Submission Form for each human subjects research protocol performed under the USSOCOM proposal. 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. Additional site-specific documents will be requested at a later date.

For questions regarding USSOCOM HRPO human research protocol review requirements or assistance in completing this form, leave a message at 813-826-7498 or hrpp@socom.mil and a staff member will contact you.

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

* *The USSOCOM HRPO defines intramural research as research conducted by DoD laboratories. All other USSSOCOM managed research is considered extramural*

Protocol Submission Form

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

1. Protocol Title:

2. Associated USSOCOM Proposal:
Proposal Log # Award # (e.g. H92222-17-C-0001)

3. HRPO Log Number (If known): S-

4. Funded Activities. Which activities in the protocol are funded by the DoD/USSOCOM?
a. ☐ All Protocol Activities
OR
b. ☐ Select activities (Describe in detail):

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.

6. Involved Institutions and Institutional Review Board (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 are interacting 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 HRPO at 813-826-7498 or hrpp@socom.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 Federal Wide Assurance # (Click here to search)	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 Determination	IRB Approved Waivers** *(Indicate: A, B, C, D)*
					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.	

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 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 proposed sites, site Principal Investigators, and IRBs in the above table. Additional site documents will be requested at a later date.

7. Research Monitor Requirements. If the protocol is considered greater than minimal risk to subjects, a research monitor must be identified. Please check one of the following:

a. ☐ Not applicable

b. ☐ Protocol is greater than minimal risk (Complete the table below)

Research Monitor	Role and Responsibilities*
Name: Affiliated Institution:	Study Role(s): Responsibilities:
Note: Please provide a current CV/Biosketch and documentation of human subjects' protection training for the Research Monitor. A Research Monitor must not be a member of the study team and is not a Clinical Research Associate (CRA). A Data Safety Monitoring Board/Data Monitoring Committee (DSMB/DMC) member may serve as the DoD required Research Monitor.	

* *Additional information about the Research Monitor's duties and responsibilities can be found in the document "**Information for Investigators: Headquarters, U. S. Special Operations Command: Human Research Protections Regulatory Requirements**)" found on USSOCOM HRPO website: https://www.socom.mil/SOF-ATL/Pages/HRPO.aspx*

8. 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 effectiveness 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 Devices. Does the protocol assess the use of a medical device?

☐ Yes (If Yes, proceed to question i)
☐ No (If No, skip to Section B (Checklist of Documents to be Submitted to HRPO))

i. Is the purpose of your protocol to evaluate the safety or effectiveness of a medical device as defined at 21 CFR 812?

☐ Yes (If Yes, continue to question ii)
☐ No (If No, skip to Section B, (Checklist of Documents to be Submitted to HRPO)

ii. 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 (If Yes, the protocol may be exempt from IDE requirements. Skip to Section B, (Checklist of Documents to be submitted to HRPO)
☐ No (If No, complete the table below)

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.			

NOTE: An Investigational device is a device that is the object of an investigation. When a protocol is research involving one or more subjects to determine the safety or effectiveness of a device, it is subject to the requirements of FDA's Investigational Device Exemption (IDE) regulations unless determined exempt from the requirements. If available, include documentation from the sponsor or FDA identifying the IDE status, IDE number.

Protocol Submission Form

Section B. Checklist of Documents to be Submitted to the ORP

PI Name:
Protocol Title:

The HRPO 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.

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 HRPO 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))
☐ Subject recruitment material (e.g., telephone recruitment script, online or print advertising)

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

☐ Scientific/Peer Review of Protocol
☐ Current Curriculum vitae or Biosketch for PI and Research Monitor (If protocol is greater than minimal risk)
☐ Documentation of human subjects training for the Principal Investigator, Co-Investigator, Associate Investigator(s), Research Monitor
☐ 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

Section C. Reporting Requirements and Responsibilities of the Principal Investigator to the USSOCOM 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.

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

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 USSOCOM 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 USSOCOM HRPO.

3. All unanticipated problems involving risk to subjects or others must be promptly reported by telephone (813-826-7498), by email (hrpp@socom.mil) to the HRPO. A complete written report will follow the initial notification.

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 USSOCOM HRPO.

5. A copy of the continuing review approval notification by the IRB of Record must be submitted to the HRPO as soon as possible after receipt. Please note that the HRPO also conducts random 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 and scan this signature page.

I have read the above reporting requirements and responsibilities of the Principal Investigator to the USSOCOM 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: