Human Research Protection Office
Headquarters, United States Special Operations Command

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Form for Determining Whether a Project Involves Human Subjects Research

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Research either supported or conducted by US Special Operations Command elements are required to conform to US SOCOM Command Policy 18-01, DoDI 3216.02, and Title 32 CFR 219. USSOCOM supported or conducted research involving human subjects must be reviewed and approved by a DoD IRB or if reviewed and approved by a non-DoD IRB, the research must also be reviewed and approved by a DoD Human Research Protection Official (HRPO). This form is intended to help a researcher determine if your project requires IRB/HRPO approval. Researchers are not authorized to make human subjects research determination, and should consult with their supporting IRB/HRPO. USSOCOM personnel may use this form and submit to the USSOCOM HRPO for review. To submit for USSOCOM HRPO review - complete the entire form, and email the signed form and any relevant supporting documents (i.e., grants, protocol, consent forms, testing materials) to hrpp@socom.mil. You should receive an HRPO response within 10 business days.

Current Status of the Project

Has the project already been conducted (i.e., data has already been collected and analyzed)?
☐ Yes ■ No

SECTION I: Activities Determined by the USSOCOM HRPO Not to Represent Human Subjects Research

A. ☐ **Health Protection/Surveillance:** The activity is carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs of the Department of Defense.

NOTE: Specifically included in this exception are systems established by DoD for health surveillance associated with deployment activities pursuant to 10 U.S. Code § 1074f and the use of medical products consistent with DoD Instruction 6200.02 (Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs).

B. ☐ **Practice of Medicine:** The activity consists of authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment.

NOTE: This exception is intended to enable the practice of medicine between a health professional and a single patient under their care. Those activities that involve the use of FDA regulated products or devices for other than their approved uses, must comply with FDA and DoD policy/regulations.

C. ☐ **Operational Test & Evaluation/Technical Experimentation:** The activity is performed solely for an OT&E project where the activities and project meet the definition of OT&E defined in 10 U.S. Code § 139. The term "operational test and evaluation" is defined as: (i) the field test, under realistic combat conditions, of any item of (or key component of) weapons, equipment, or munitions for the purpose of determining the effectiveness and suitability of the weapons, equipment, or munitions for use in combat by typical military users; and (ii) the evaluation of the results of such test.

NOTE: This exception includes Human Participant(s) in Testing and Evaluation/Experimentation activities. This is defined as a living individual used to affect a test activity through intervention or interaction with the individual, but whom is not the subject of the activity. Focus data collected is not about the individual, but rather is about the object or design being tested. If the human participant is the subject of the activity or if focus data is collected about the individual the activity will require IRB/HRPO review and approval.

D. ☐ **Occupational Health and Safety:** The activity is performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information.

E. ☐ **Program Evaluation / Review:** Activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended to be generalized beyond such program.

NOTE: This exception allows DoD Programs to conduct programmatic performance reviews. Key aspects of this exception include any survey's being used should be anonymous, and results of such activity are to be used internally to DoD for program improvement. If the intent is to publish or share results outside of DoD the activity would likely be considered human subjects research and require IRB/HRPO review.

F. ☐ **Intelligence/Information Operations:** Survey, interview, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by DoDD 5240.01 (DoD Intelligence Activities). Survey, interview, or surveillance activities and related analyses performed solely for authorized information operations purposes, as authorized by DoDD 3600.01 (Information Operations).

NOTE: This exception allows for authorized foreign intelligence and information operations activities.

G. ☐ **Case Study/Report:** The project consists of a case report or series which describes an interesting treatment, presentation or outcome. A critical component is that nothing was done to the patient(s) with prior "research" intent.

NOTE: For case reports, HIPAA requires that the disclosure of an individual's protected health

information must be authorized by that individual. If a case report contains any of the 18 protected health information identifiers as defined by the HIPAA regulations, a signed authorization (using the authorization form from the entity that holds the record) to disclose this information must be obtained from the individual(s) whose information is being disclosed.

H. ☐ **Course-Related Activities:** The project is limited to course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of a routine class exercise or assignment and is not intended for use outside of the classroom.

NOTE: IRB/HRPO approval **is** required if a student is involved in an activity designed to teach research methodologies and the instructor or student wishes to conduct further investigation and analyses in order to contribute to scholarly knowledge.

I. ☐ **Decedents:** The project involves research that is limited to death records, autopsy materials, or cadaver specimens. If the project involves the use and/or collection of Protected Health Information (PHI), HIPAA regulations apply to decedent research. As the Privacy Board, the IRB Office requires that you confirm the following conditions as set forth in the Privacy Rule at 45 CFR 164.512(i)(ii)(iii), have been met.

i. ☐ the use will be solely for research on the information of a decedent; and
ii. ☐ the Principal Investigator has documentation of the death of the individual about whom information is being sought, and
iii. ☐ the information sought is for the purposes of the research

Note, however, that this exception may not be available for decedent Information that contains Psychotherapy Notes or Information relating to HIV, mental health, genetic testing, or drug or alcohol abuse.

J. ☐ **Program evaluation /Quality Improvement/Quality Assurance Activities:** The project is limited to program evaluation, quality improvement or quality assurance activities designed specifically to assess or improve performance within the department, hospital or classroom setting. The intention of the project is not to generate conclusions that can be applied universally, outside of the immediate environment where the project occurred.

Note: Investigators who plan to conduct a QI/QA project, should ensure that they have received approval from any applicable committees within their department or the site in which the activity will occur.

K. ☐ **Public Use Datasets:** The project is limited to analyzing de-identified data contained within a publicly available dataset.

Note: IRB/HRPO review is required if the publicly available data set contains identifiable information, or if the merging of datasets might result in identification of subjects.

L. ☐ **De-Identified Private Information or Human Biological Specimens:** The project is limited to the use of existing and/or prospectively collected de-identified private information and/or human biological specimens (hereafter referred to as "specimens"). IRB Approval is not required if you

can confirm the following:

i. ☐ The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and**

ii. ☐ The investigator can confirm that the use of the private information or specimens is not in violation of the terms of use under which the information or specimens were/will be collected; **and**

iii. ☐ The investigator will only receive information or specimens that are fully de-identified. De-identified means that the materials to be studied are devoid of any of the 18 Protected Health Information elements set forth in the Privacy Rule, as well as any codes that would enable linkage of the information or specimens to individual identifiers. Note: To be considered de-identified, nobody, including individuals who are not involved in the conduct of the project, should be able to link the information or specimens back to identifiers. **and**

iv. ☐ Specimens are <u>not</u> being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, **and**

v. ☐ The records/images/charts that are being collected for this study are <u>not</u> from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.

Instructions: If your activity did not fall into the categories described in Section I, continue to Section II and III to assess if you are engaged in human subjects research per the regulations set forth by the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA).

SECTION II. Activities subject to DoD and HHS human subject research regulations (DoD Directive 3216.02 & 45 CFR 46)

1. **Is the activity RESEARCH: a systematic investigation designed to contribute to generalizable knowledge?**

   TIP: If the investigation characterized by order, planning, and methodology and the intention of the investigation is to generate conclusions that can be applied broadly or universally, outside of the immediate environment where the investigation occurred (i.e., the classroom, unit, department), then the activity meets the definition of research.

   ☐ Yes, Go to #2 ☐ No, Go to FDA section III

2. **Does the research involve obtaining information about LIVING individuals?**
   ☐ Yes, Go to #3 ☐ No, Go to FDA section III

3. **Does the research involve collecting data through <u>intervention</u> (i.e., physical procedures or manipulation of the environment) or <u>interaction</u> (i.e., communication or interpersonal contact between investigator and person) with the individuals?**
   ☐ Yes, **IRB/HRPO review required.** ☐ No, Go to #4
   Go to FDA section III to assess if FDA regulations apply to your study.

4. **Does the research involve collecting identifiable information (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)?**
   ☐ Yes, Go to #5 ☐ No, Go to FDA section III

5. **Is the information <u>private</u>? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public)**
   ☐ Yes, **IRB review required** ☐ No, Go to FDA section III
   Go to FDA section III to assess if FDA regulations apply to your study.

SECTION III. Activities subject to FDA human subject regulations: If your answer is "yes" to any of the 3 questions below, IRB approval is required and the FDA regulations apply to your study.

1. Is this is an experiment that involves a test article* and one or more human subjects, and the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit (PMA, 510K)? A subject is an individual (either

health or a patient) who is a recipient of the test article or a control.

*Test article *Test article* means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug, and Cosmetic Act.

Note: If the test article is a drug, biologic, or device that is ultimately targeting FDA clearance/approval for SOCOM/DoD use select Yes below.

☐ Yes , **IRB review required** ☐ No

2. Is this is a clinical investigation or research involving one or more human subjects to determine the safety or effectiveness of a device? A subject is an individual (healthy or has a medical condition or disease) on whom or on whose specimen an investigational device is used, or who participates as a control.

   ☐ Yes, **IRB review required** ☐ No

3. Is this an experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects? This excludes the use of a marketed drug in the course of medical practice. A human subject is an individual (healthy or patient with a disease) that participates either as a recipient of the investigational new drug or as a control.

   ☐ Yes, **IRB review required** ☐ No

Instructions:
If IRB Review is required, regardless of FDA applicablity, the investigator must find an appropriate IRB with a federal assurance to review the activity.

SECTION IV: Complete this section if you believe that your activities do not constitute human subjects research or may be exempt and you require written confirmation of this determination from the HRPO Office. E-mail the signed form and any relevant supporting documents (i.e., grant, protocol, consent forms) to hrpp@socom.mil.		
Investigator Information		
Name (Last, First)	Degree(s)	University Status/Title
Department		College
Phone Number		E-mail Address
Project Information		
Project Title		
Name of Funding Source (i.e., Department, NIH, Foundation)		
Grant Number (if applicable)		
Project Description (describe the aims of the study and any activities involving interaction, intervention with human subjects, and/or their information or specimens)		

Signature of Investigator: _____

Date: _____

SECTION V: HRPO Determination (to be completed by HRPO)*

The activities as described in the ☐ submitted protocol and/or ☐ materials and description of activities provided by the investigator,

☐ **Do not constitute research with human subjects in accordance with 45 CFR 46 and 21 CFR 50 & 56. IRB approval is not required.**

☐ **For activities involving decedents and their Protected Health Information (PHI), the conditions as set forth in the Privacy Rule at 45 CFR 164.512(i)(l)(iii), have been met.**

- the use or disclosure sought is solely for research on the protected health information of decedents;
- documentation can be provided, at the request of the covered entity, of the death of such individuals; and
- the protected health information for which use or disclosure is sought is necessary for the research purposes.

HRPP Reviewer Personnel Printed Name: _____

HRPP Reviewer Personnel Signature: _____

USSOCOM HRPO Printed Name: Howard Strahan Jr.

Authorized HRPO Personnel Signature: _____

Title: Deputy S&T / HRPO

Date: _____

*If any activities completed were or possibly were not in compliance with federal regulations regarding prior IRB review, please forward the form to the USSOCOM HRPO for review. For example, the investigator reports activities which are already completed but initially required IRB approval.