

**Department of Defense Supported Research****SOP****I. PURPOSE**

Research supported by the Department of Defense (DoD), including its separate components, or recruiting DoD personnel requires compliance with additional federal regulations, directives and instructions. This procedure applies to human research that is funded by or recruits participants from the DoD or a DoD component through a contract, grant, cooperative agreement or other arrangement.

**II. POLICY STATEMENT**

When research is funded by the DoD, the IRB will apply the regulations at 32 CFR 219, as well as the additional requirements of 10 USC 980 and the DoD Directive, 3216.02.

**III. SCOPE**

These policies and procedures apply to all research conducted by the US Department of Defense where the CHOP IRB serves as the Reviewing IRB.

**IV. DEFINITIONS**

DoD: Department of Defense

Minimal Risk: Defined as "...the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests...." (§46.102(i)). The IRB interprets "minimal risk" to be calibrated to the life of normal, healthy children and "daily life" to be those activities to which most children are exposed. The IRB may determine that procedures that are considered minimal risk for normal healthy children constitute greater than minimal risk for populations that are vulnerable by virtue of their condition or circumstances.

Prisoner of War: DoD definition of Prisoner of War is any person captured, detained, held or otherwise under the control of DoD personnel (military and civilian, or contractor employee).

Research Involving a Human Being as an Experimental Subject: The DoD definition states that "An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32CFR.219.102 (f)". Research involving a human being as an experimental subject is a subset of research involving human subjects. Examples of interventions or interactions include, but are not limited to, a physical procedure, a drug, a manipulation of the subject or subject's environment, the withholding of an intervention that would have been undertaken if not for the research purpose.

Activities exempt under the Common Rule are not included in the definition of research involving a human being as an experimental subject (DoD Directive 3216.02).

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**V. PROCEDURES****A. Categories of Research Funded by the DoD Where the CHOP IRB will not Serve as the Reviewing IRB.**

The CHOP IRB will not serve as the Reviewing IRB for prospective research that involves Department of Defense personnel, including U.S. military personnel. This does not preclude the CHOP IRB from serving as the Reviewing IRB for research where the involvement of U.S. military personnel is limited to review of their medical or other records.

Research involving Prisoners of War is prohibited, regardless of funding source.

**B. Education Requirements**

Initial and continuing research ethics education is required for all personnel who conduct, review, approve, oversee, support or manage human research supported by the DoD or its components.

The CHOP Research Institute, Department of Research Education and Training requires initial CITI training for all research personnel and IRB members and requires specified CITI refresher course training every three years. Note however, individual DoD components may have stricter or specific educational requirements. Researchers will be advised to contact their project coordinators at the DoD, or DoD component, to ensure adherence to any unique requirements.

The IRB staff will ensure that training requirements for research team members are current at the time of review of protocols funded by the DoD.

**C. Multi-site Research**

When conducting multi-site research, the supplement must clearly detail the roles and responsibilities of each party at each site involved in the research. The CHOP IRB can aid the CHOP researcher in developing a formal agreement should one be required by the DoD or one of its components.

**D. Research Monitor**

Appointment of an independent research monitor is required for research involving greater than minimal risk. The monitor must be a physician, dentist, psychologist, nurse, or other healthcare provider capable of overseeing the progress of the research protocol, especially issues of individual subject/patient management and safety. The monitor must be independent of the investigative team and possess sufficient educational and professional experience to serve as the subject/patient advocate. The Principal Investigator is responsible for providing the name, contact information and responsibilities of the monitor to the IRB in the IRB application. Note however, that the IRB may require a monitor for a portion of the project or for studies involving no more than minimal risk when appropriate.

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At the discretion of the IRB, the research monitor may be assigned to discuss research progress with the principal investigator, interview subjects, consult on individual cases, or evaluate adverse event reports. Research monitors shall promptly report discrepancies or problems to the IRB.

The research monitor has the authority to stop a research study in progress, remove individuals from a study, and/or take any steps to protect the safety and well-being of subjects until the IRB can make an assessment.

**E. Research-related Injury**

The Department of Defense components may have stricter requirements regarding care and treatment for research-related injury than outlined in the federal regulations at 45 CFR 46. In general, CHOP will commit to providing or arranging for treatment to research volunteers. Investigators must work with their project coordinator within the DoD component and CHOP Technology Transfer Office to identify the specific requirements for treatment of research-related injury.

The required consent language for research-related injury in the DoD contract will supplement that specified in **SOP 701**.

**F. Scientific Review**

New research and substantive amendments to approved research must undergo scientific review prior to or at the time of ethics (IRB) review. When research is limited to the review of medical records or existing data sets, the DoD review of the grant will be accepted as the scientific review.

An amendment to approved research will be considered substantive if it doesn't meet the criteria for expedited review as outlined in **Appendix 1, SOP 401** or if it does not meet the criteria for a Minor Amendment in **Appendix 2 to SOP 401**.

**G. International Research**

When the research will take place at one or more international sites, the IRB and the investigator will also adhere to the requirements of **SOP 411**. Specifically, the investigator must obtain and provide evidence of local IRB approval and must follow all local laws, regulations, customs, and practices.

**H. Waiver of Informed Consent**

When research is funded by the DoD or its components and includes "experimental subjects", a waiver of consent by the IRB is prohibited, unless a waiver is first obtained from the Assistant Secretary of Defense for Research and Engineering as allowed by 10 USC 980(b). If the research subjects are not "experimental subjects" the IRB may waive consent as outlined in **SOP 701**.

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**I. Reporting of Non-Compliance**

Serious and continuing non-compliance that occurs in research funded by the DoD will be reported to OHRP and the FDA as outlined in **SOP 901** and to the DoD Component funding the research. The procedures for assessing and reporting non-compliance will follow those outlined in **SOP 901**.

**VI. APPLICABLE REGULATIONS AND GUIDELINES**

32 CFR 219	DoD Directive 3216.02
10 USC 980	

**VII. REFERENCES TO OTHER APPLICABLE SOPS**

SOP 401: Expedited Review Procedure	SOP 701: Required Elements of Consent and Documentation of Consent
SOP 411: International Research	SOP 901: Non Compliance with Human Subjects Research Policy

**VIII. RESPONSIBILITIES**

<b>Title</b>	<b>Responsibility</b>
Director, HSR	Responsible for ensuring that research funded by the DoD meets the unique requirements as outlined in the regulations.
Chair, CPHS	Responsible for ensuring that the IRB makes all additional determinations and ensuring that the unique requirements are included when reviewing research funded by the DoD.

**IX. ATTACHMENTS**

The CHOP IRB's website provides copies and links to references related to DoD regulations including:

10 USC 980, 32 CFR 219 and DoD Directive 3216.02

<https://irb.research.chop.edu/regulations-resources>

**Department of Defense Supported Research****SOP****X. REVISIONS/REVIEWS:**

- 07-08-2010: Initial Approval Date:
- 09-25-2012: Clarified when CHOP will serve as the IRB of record for research that involves Department of Defense personnel.
- 07-24-2014: Revised to include minimal risk definition and other administrative edits.
- 01-22-2018 Revised to include updated CHOP logo, edits to the waiver of consent section and correct list of SOPs referenced in this document.
- 03-19-2018 Revised to include the Assistant Secretary of Defense for Research and Engineering and to clarify when consent may be waived.
- 06-07-2021 Revised to make minor edits and for consistency with other relevant SOPs.

**XI. APPROVAL**

Approved by: Approved by Amy Schwarzhoff and Barbara Engel on 06/07/2021

Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, IRB Research