



Research Involving Department of Defense Funding

Purpose

The purpose of this document is to provide guidance to Children's Hospital Boston (CHB) researchers whose human subjects research involves any component of the Department of Defense (DoD) funding or support

Scope and Applicability

This information and guidance applies to all human subjects research involving the DoD. Research is considered to involve the Department of Defense when:

- A. The research is funded by a component of DoD.
- B. The research involves cooperation, collaboration, or other type of agreement with any component of DoD.
- C. The research uses property, facilities, or assets of a component of DoD.
- D. The subject population will intentionally include personnel (military and/or civilian) from a component of DoD.

Children's Hospital does not conduct research involving military personnel. *DoD policies and requirements do not apply when DoD personnel incidentally participate as subjects in research that is not supported by DoD, and DoD personnel are not an intended population of the research.*

Background

In the past few years, DoD has significantly enhanced their human subjects protection requirements, including the application of those requirements to researchers who are not employees of the DOD. From time to time CHB investigators will receive funds from DoD and therefore the additional regulations will apply. Example A describes the type of DoD research that is most frequently conducted at CHB to date. Examples B-D are much less common. As necessary and requested by DoD, Children's Hospital will sign an Addendum to its Federalwide Assurance (FWA). This document requires that CHB apply Department of Defense (DoD) regulations and policies for the protection of human research subjects when conducting, reviewing, approving, overseeing, supporting or managing human subjects research involving the DoD. DoD directive 3216.2 provides the hospital with the additional DoD requirements.

Principal investigators (PI) will need to include in their protocol the additional information required so that the IRB may take into consideration the additional DoD requirements and determinations. DoD will require documentation of Institutional

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Review Board (IRB) approval, the risk level, and the expiration date of the research to the DoD Component sponsoring or supporting the study. The DoD may also request additional documentation to verify compliance with federal and DoD policies, including minutes related to the research, any exemption determinations, or documentation of continuing approval. The DoD applies the provisions in 45 CFR Part 46, Subparts B, C, and D for the protection of vulnerable classes of subjects but prohibits the use of prisoners of war in DoD sponsored research. Research that involves greater than minimal risk requires appointment of an independent research monitor. In certain cases, the DoD also applies limitations on the waiver of informed consent.

Definitions

Research Involving a Human Being as an Experimental Subject is defined as 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 [32 CFR 219.102(f), reference (c)]. Examples 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.

DoD Components refers collectively to the organizational entities within the DoD that are subject to the human subjects protections laid out in Department of Defense Directive

Research Monitor refers to a physician, dentist, psychologist, nurse, or other healthcare provider designated to oversee a specific protocol that involves more than minimal risk, especially issues of individual subject/patient management and safety. The research monitor functions independently of the research team and shall possess sufficient educational and professional experience to serve as the subject/patient advocate.

Specific considerations and procedures for DOD research

1. Scientific Review :

DoD requires scientific review prior to IRB review for all new DoD supported human research. The Children's Hospital policy (**Department/Division Scientific Review of Human Subjects Research**) that requires Departmental scientific review prior to IRB submission meets this requirement. DoD also requires that all substantive amendments to approved DoD research involving human subjects receive scientific review prior to IRB review. Substantial amendments must be submitted for departmental review prior to submission to the IRB, Changes that do not qualify as minor in the CHB policy (**Revisions and Amendments**) and are submitted to the full IRB constitute substantial amendments

2. Education Requirements

The Clinical Investigation Policy and Procedure Manual



Children's Hospital Boston

Document: CIPP 014.001

DOD requires initial and continuing mandatory education requirements for human subjects protections. The Children's hospital requirements for mandatory and continuing education meet this requirement. (**Education and Training: Investigators and Research Staff**)

3. **Research Monitor Required: Greater than Minimal Risk Studies**

For DoD-sponsored research involving greater than minimal risk to subjects, the DOD requires appointment of an independent research monitor. The research monitor has the authority to: 1) Stop a research study in progress; 2) Remove individuals from the study; 3) Take any steps to protect the safety and well-being of subjects until the IRB can assess the research monitor's report. The PI in coordination with the IRB identifies a candidate for the position of research monitor, taking into account the nature and disciplinary focus of the study and the likely type of medical expertise required. The IRB also ensures that the research monitor is independent of the research team.

4. **Research Involving International Citizen Populations:**

For research conducted internationally the Children's Hospital policy for international research (**International Research and Cross Cultural Issues**) will meet the DOD requirements. This includes taking into consideration subject populations, the cultural context, the languages understood by the human subjects, identifying and considering local laws, regulations, customs and practices. In addition determinations are made as to whether the sponsoring DoD Component requires an additional ethics review by the host country or a local DoD IRB with host country representation. Children's Hospital, Boston or the investigator will also require permission to conduct research in that country by certification or local ethics review

5. **Waiver of Consent and Exception from Informed Consent in Emergency Medicine**

If a research subject meets the definition of "experimental subject," DoD regulations prohibit a waiver of consent unless the PI obtains a waiver from the Secretary of Defense. The IRB may waive the consent process if the research does not meet the definition of "experimental subject." DoD regulations prohibit an exception from informed consent in emergency medicine research unless the PI obtains a waiver from the Secretary of Defense.

6. **Multi-Site or Collaborative Research Requirements**

Any investigator developing a proposal for DoD funding or other support that involves other collaborating institutions needs to consult the sponsoring DoD Component and ORI staff to identify additional requirements for multi-site research. Formal agreements may be necessary to ensure that participating institutions understand and accept their scope of work specific roles and responsibilities of each party are agreed upon. The CHB policies for reliance agreements could be considered for DOD funded research.

7. **Provisions for Research-related Injury**

The Clinical Investigation Policy and Procedure Manual



Children's Hospital Boston

Document: CIPP 014.001

The PI is responsible for informing the IRB if there are any requirements from DoD Component's the provision of care in the case of a research-related injury. If the DoD Component has stricter requirements than the Common Rule or CHB policies this will need to be discussed and agreed upon by General Counsel and the VP of Research Administration. These requirements will also need to be disclosed in the informed consent document

8. **Research Involving U.S. Military Personnel as Research Participants;**

If any research includes U.S. military personnel as subjects the IRB protocol must include a plan for research subject recruitment that incorporates additional safeguards to minimize undue influence from individuals within a potential subject's chain of command. The PI is required to consult with the sponsoring DoD Component to determine appropriate recruitment plans. In addition unless on leave status during research participation, military personnel may not receive compensation for their participation

9. **Under no circumstances shall the IRB approve research involving prisoners of war, as defined by the specific DoD Component.**

10. **Additional DoD Review Required Prior to Initiation of Study**

After the IRB completes its review and issues approval, the PI through the Office of Sponsored programs will need to submit documentation of IRB approval, the risk level, and the expiration date of the research to the DoD Component sponsoring or supporting the study. The DoD may also request additional documentation to verify compliance with federal and DoD policies, including minutes related to the research.

The PI may not initiate the study until the human research protection officer within the sponsoring DoD Component reviews and approves the IRB approval and other submitted documentation.

If the study is for DoD-sponsored survey research or survey research within the DoD that involves DoD personnel, including military personnel, an additional level of DoD review of the study may be required. Surveys typically require DoD Survey Review and approval. The PI submits surveys and all required documentation relevant to survey research review to the requesting DoD Component.

Regulatory Citations:

32 CFR 219, "Protection of Human Subjects"

Department of Defense (DoD) Directive 3216.2, "Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research"

The Clinical Investigation Policy and Procedure Manual



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Document Attributes

Title	Research Involving Department of Defense Funding		
Author	Susan Kornetsky	Dates Reviewed/ Revised	08/15/2010
Reviewed/ Revised by	Susan Kornetsky	Last Modified	10.29.2010
Copyright	@Children's Hospital Boston, 2012		
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