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Human Research Protection Program

Institutional Review Board (IRB) Researcher Education Series

IRB CONCERNS WHEN CONDUCTING DEPARTMENT OF DEFENSE RESEARCH

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DoD Office of Human Research Protections (DOHRP)

DOHRP resides in the office of the Under Secretary of Defense for Research & Engineering.

Mission: Foster globally leading research, ensuring technological advantage for the U.S. warfighter and the well-being of warfighters, their families, and the public.

The DoD has adopted the Common Rule as well as additional safeguards specific to DoD Research projects.

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DoD Research: Applicable Regulations

DHHS Revised Common Rule

DoD Instruction 3216.02 *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research.* Non-exempt classified research must be conducted following the requirements of listed in DoDI 3216.02 13.

32 CFR 219 *Protection of Human Subjects (Department of Defense)*

LSUHSC Policies & Procedures 4.12 *Additional Requirements for Department of Defense (DOD) Research*

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What is Considered DoD Research?

The research is funded by a component of the DoD

and/or

The research involves cooperation, collaboration or another type of agreement with a component of DoD

and/or

The research uses property, facilities or assets of a component of DoD

and/or

The subject population will intentionally include personnel (military and/or civilian) from a component of DoD

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Before Starting DoD Research

Local IRB approval must be obtained and provided to the DoD

The DoD Human Research Protection Official (HRPO) must provide a written determination

Contracts must be negotiated with all parties, both DoD and non-DoD. If conducting multi-site research, a formal agreement between non-DoD organizations is required and must specify the roles and responsibilities of each party

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Consenting Subjects for DoD Research

The Informed Consent of the subject must be obtained in advance of any research activities

In addition to the basic required consent disclosures, consents for DoD-supported research must include:

- A statement that the DoD or a DoD organization is funding the research.
- A statement that representatives of the DoD are authorized to review the records.

If consent is to be obtained from the experimental subjects' legal representative, the research must intend to benefit the individual participant. The determination that research is intended to be beneficial to the individual experimental subject will be made by the IRB

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Experimental Subjects

An “experimental subject” is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. If the research participant meets the IRB definition of “experimental subject,” a waiver of the consent process is prohibited unless a waiver is obtained from the Assistant Secretary of Defense for Research and Engineering. Research involving “experimental subjects” as defined in DODI 3216.02 is a subset of research involving human participants.

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Experimental Subjects

The Assistant Secretary for Defense for Research and Engineering may waive the requirements for consent when all of the following are met:

- The research is necessary to advance the development of a medical product for the Military Services.
- The research may directly benefit the individual experimental subject.
- The research is conducted in compliance with all other applicable laws and regulations.

For classified research, waivers of consent are prohibited.

If the research participant does not meet the definition of “experimental subject,” policies and procedures allow the IRB or EC to waive the consent process.

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DoD Personnel as Subjects: Undue Influence

When research involves U.S. military personnel, research protocols will include the following guidelines for additional protections for military research participants to minimize undue influence:

- Officers are not permitted to influence the decision of their subordinates.
- Officers and senior non-commissioned officers may not be present at the time of recruitment.
- Officers and senior non-commissioned officers have a separate opportunity to participate.
- When recruitment involves a percentage of a unit, an independent ombudsman is present.

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DoD Personnel as Subjects: Compensation

When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:

- Prohibit an individual from receiving pay of compensation for research during duty hours.
- An individual may be compensated for research if the participant is involved in the research when not on duty.
- Federal employees while on duty and nonfederal persons may be compensated for blood draws for research up to $50 for each blood draw.
- Non-federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

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Reporting to the DoD HRPO

Surveys performed on DoD personnel will be submitted, reviewed, and approved by the DoD after the research protocol is reviewed and approved by the IRB.

The following will be promptly (no longer than within 30 days) reported to the DoD human research protection officer:

- When significant changes to the research protocol are approved by the IRB.
- The results of the IRB continuing review.
- Change of reviewing IRB.
- When the organization is notified by any federal department, agency or national organization that any part of an HRPP is under investigation for cause involving a DoD supported research protocol.

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Reporting to the DoD HRPO continued

Any determinations of serious or continuing noncompliance of DoD-supported research will be promptly (no longer than within 30 days) reported to the DoD human research protection officer

Any unanticipated problems involving risks to participants or others for any DoD-supported research will be promptly (no longer than within 30 days) reported to the DoD human research protection officer.

Any suspension or termination of DoD supported research will be promptly (no longer than within 30 days) reported to the DoD human research protection officer

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Research Monitor

A Research monitor will be appointed for research involving greater than minimal risk.

The monitor must be appointed by name and must be independent of the team conducting the research.

There can be more than one monitor appointed, if different skills or experience is needed.

The monitor may be an ombudsman or a member of the data safety monitoring board. The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities

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Research Monitor Duties

The IRB or HRPP official must communicate with research monitors to confirm their duties, authorities, and responsibilities.

The duties of the research monitor are determined on the basis of specific risks or concerns about the research:

- May perform oversight functions
- May discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study
- Report observations and findings to the IRB or a designated official

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Authority of Research Monitor

The research monitor has the authority to:

- Stop a research study in progress.
- Remove individuals from study.
- Take any steps to protect the safety and wellbeing of participants until the IRB can assess.

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subpart B: Pregnant Women, Fetuses, & Neonates

DoD research involving pregnant women, fetuses, & neonates must comply with subpart B of 45 CFR 46, with the following modifications:

- For purposes of applying Subpart B, the phrase “biomedical knowledge” must be replaced with “generalizable knowledge.”
- The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.

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Unique DoD Research Rules

Research involving a detainee, as defined in DoD Directive 2310.01E, or a prisoner of war as a human subject is prohibited.

Research involving large-scale genomic data collection from DoD personnel is subject to component security review and DOHRP approval as disclosure of the data may pose a national security risk.

Use of a single IRB in accordance with 32 CFR 219.114 is required. Exceptions may be made by the DoD Component's OHRP.

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Additional Resources

Department of Defense - Congressionally Directed Medical Research Programs:
https://cdmrp.army.mil/

Human Subjects Research Definitions, Categories, and Resource Information:
https://cdmrp.army.mil/pubs/pdf/Human%20Subjects%20Resource%20Document.pdf

LSUHSC - NO HRPP Policies and Procedures 4.12
https://www.lsuhsc.edu/administration/academic/ors/policies_procedures.aspx