



Research Regulatory Oversight Office

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INFORMATION PAPER

Human Research Protection Official Review of Contracted Work

*Information Papers published by the OUSD(P&R), R2O2 contain background information on specific issues raised to this Office, policies covering the issues and the OUSD(P&R), R2O2 interpretation of those policies. These papers include policy interpretations that are enforceable within and among all institutions in the OUSD(P&R).*

Background

When a Department of Defense (DoD) institution is supporting research involving human subjects that is conducted by a non-DoD institution, the DoD institution must ensure the institution conducting the research involving human subjects is aware of its obligation to comply with the requirements of DoD Instruction (DoDI) 3216.02 and 32 CFR 219.

Policy

In accordance with Enclosure 3, Section 4.a of DoDI 3216.02, contracts for DoD-supported research involving human subjects must contain the Defense Federal Acquisition Regulation Supplement (DFARS) clause identified at section 252.235-7004 of Title 48, Code of Federal Regulations. In addition to identifying contractor requirements and responsibilities, the clause also describes the role of the DoD Human Research Protection Official (HRPO), which it defines as "...the official who is responsible for the oversight and execution of the requirements of this clause." Furthermore, Enclosure 3, Section 4.c of DoDI 3216.02 extends this policy to other types of agreements (aside from contracts), so a "HRPO-like" review must be conducted by the HRPO of all DoD-supported when the primary IRB is a non-DoD IRB. Additional details can be found in PG-01-005 dated 23 March 2015.

Implementation Requirements

When the contract or other agreement may include research involving human subjects and if the non-DoD institution determines either the activity is not research involving human subjects or is exempt research involving human subjects, the HRPO must concur with the performing institution's determination before activity can begin. If the non-DoD institution determines the activity is non-exempt research involving human subjects, then at a minimum, the HRPO must:

- 1) Confirm the non-DoD institution has a Federal assurance appropriate for the research in question.
- 2) Review the research protocol and accept the Institutional Review Board (IRB) determination of level of risk and approval of the study for compliance with this DoDI 3216.02.
- 3) Review and accept IRB-approved substantive changes to an approved research protocol before they are implemented.
- 4) Ensure the IRB conducts an appropriate continuing review at least annually.
- 5) When the research involving human subjects is being conducted in a foreign country, confirm all applicable national laws and requirements of the foreign country have been met and confirm the IRB considered the cultural sensitivities in the setting where the research will take place.

Submission Requirements

A complete package includes each of the following documents:

- IRB Documentation:
  - Protocol, including all attachments, approved by the primary IRB for the study (including the scientific review for all non-exempt studies and any advertisements, questionnaires and interview scripts that will be utilized in the study)
  - Copy of IRB approval letter(s) for the study (initial review and continuing reviews when applicable)
  - Contact Information for the PI *AND* the Government Project Manager
- Description of the PI’s affiliations and qualifications (CV/Biosketch)
- Proof of HRPP Training within the past 3 years for all researchers (available at [www.citiprogram.org](http://www.citiprogram.org) under “Office of the Under Secretary of Defense for Personnel and Readiness). If you have completed training provided by your institution, then you need only complete the DoD Specific CITI Training Module
- Signed “Researcher Responsibilities Form” for all investigators.

Definitions

**DoD-Supported Research Involving Human Subjects:** Research involving human subjects for which the Department of Defense is providing at least some of the resources. Resources may include but are not limited to funding, facilities, equipment, personnel (investigators or other personnel performing tasks identified in the research protocol), access to or information about DoD personnel for recruitment, or identifiable data or specimens from living individuals. It includes both DoD-conducted research involving human subjects (intramural research) and research conducted by a non-DoD institution.

**HRPO:** An individual who is delegated the responsibilities as defined in paragraph (a)(2) of section 252.235-7004 of title 48, Code of Federal Regulations. There may be more than one HRPO in a DoD Component. Some DoD Components may use a different title for the person(s) with the defined responsibilities.

**Human Subject:** A living individual about whom an investigator (whether professional or student) conducting research obtains: 1) Data through intervention or interaction with the individual or 2) Identifiable private information. (32 CFR 219.102(f)).

**Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (32 CFR 219.102(d)).



## DFARS Clause

Per paragraph (f) below, “the Contractor shall include the substance of this clause...in all subcontracts that may include research involving human subjects...”

- (b) The Contractor shall oversee the execution of the research to ensure compliance with this clause. The Contractor shall comply fully with 32 CFR Part 219 and DoD Directive 3216.02, applicable DoD component policies, 10 U.S.C. 980, and, when applicable, Food and Drug Administration policies and regulations.
- (c) The Contractor shall not commence performance of research involving human subjects that is covered under 32 CFR Part 219 or that meets exemption criteria under 32 CFR 219.101(b), or expend funding on such effort, until and unless the conditions of either the following paragraph (c)(1) or (c)(2) have been met:
  - 1) The Contractor furnishes to the HRPO, with a copy to the Contracting Officer, an assurance of compliance and IRB approval and receives notification from the Contracting Officer that the HRPO has approved the assurance as appropriate for the research under the Statement of Work and also that the HRPO has reviewed the protocol and accepted the IRB approval for compliance with the DoD component policies. The Contractor may furnish evidence of an existing assurance of compliance for acceptance by the HRPO, if an appropriate assurance has been approved in connection with previous research. The Contractor shall notify the Contracting Officer immediately of any suspensions or terminations of the assurance.
  - 2) The Contractor furnishes to the HRPO, with a copy to the Contracting Officer, a determination that the human research proposed meets exemption criteria in 32 CFR 219.101(b) and receives written notification from the Contracting Officer that the exemption is determined acceptable. The determination shall include citation of the exemption category under 32 CFR 219.101(b) and a rationale statement. In the event of a disagreement regarding the Contractor's furnished exemption determination, the HRPO retains final judgment on what research activities or classes of research are covered or are exempt under the contract.
- (d) DoD staff, consultants, and advisory groups may independently review and inspect the Contractor's research and research procedures involving human subjects and, based on such findings, DoD may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoD procedures.
- (e) Failure of the Contractor to comply with the requirements of this clause will result in the issuance of a stop-work order under Federal Acquisition Regulation clause 52.242-15 to immediately suspend, in whole or in part, work and further payment under this contract, or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the Contracting Officer.
- (f) The Contractor shall include the substance of this clause, including this paragraph (f), in all subcontracts that may include research involving human subjects in accordance with 32 CFR Part 219, DoD Directive 3216.02, and 10 U.S.C. 980, including research that meets exemption criteria under 32 CFR 219.101(b). This clause does not apply to subcontracts that involve only the use of cadaver materials.

