



HEALTH AFFAIRS

## OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

23 March 2015

### MEMORANDUM FOR OFFICE OF THE UNDER SECRETARY OF DEFENSE FOR PERSONNEL AND READINESS (OUSDP&R) INSTITUTIONS CONDUCTING OR SUPPORTING HUMAN SUBJECTS RESEARCH

**SUBJECT:** Duplicate, Human Research Protection Official (HRPO) and Administrative  
Reviews

The Office of the Under Secretary of Defense for Personnel and Readiness (OUSDP&R) issues Assurances for the Protection of Human Subjects (Assurance) through the Research Regulatory Oversight Office (R2O2) in accordance with DoD Instruction (DoDI) 3216.02. The OUSDP&R Component-level policy through which DoDI 3216.02 is implemented throughout OUSDP&R institutions is the *Human Research Protection Program Operating Instruction* (OI) dated September 29, 2014. Each of these policy documents describes the requirements for review of studies that may be defined as research involving human subjects.

Both the DoDI 3216.02 (Enclosure 3, Section 1.c.(4)) and the OUSDP&R OI (Sections 13.2.g. and 16.2) seek to reduce redundancy with respect to reviews of studies by DoD Institutional Review Boards (IRB). The OUSDP&R OI requires that prior written approval from the Director, R2O2 be obtained for an OUSDP&R institution to conduct a second IRB review of a study that has already been approved by a DoD IRB. Therefore, it is the position of R2O2 that duplicate reviews of studies that have been approved by another DoD IRB are not permitted within OUSDP&R institutions. Should an institutional Human Research Protection Program staff member believe that sufficient justification exists to conduct a second review, then that request will be submitted to the Director, R2O2 in writing ([R2O2@mail.mil](mailto:R2O2@mail.mil)) and the second review will only be conducted once approval of the request for exception to this policy is received from the Director, R2O2 or designee.

Title 48, Code of Federal Regulation (CFR), Sections 2.101 and 252.235-4007 includes a clause that must be included in all contracts between the DoD and non-DoD vendors that might include research involving human subjects (Defense Federal Acquisition Regulation Supplement (DFARS) clause). The DFARS clause requires the DoD to conduct a Human Research Protection Official (HRPO) review of study documents to ensure that the study is compliant with DoD-specific requirements beyond those articulated in the Common Rule (32 CFR 219). Both the DoDI 3216.02 (Enclosure 3, Section 4) and the OUSDP&R OI (Section 17) extend this type of review to other studies that include collaboration with non-DoD institutions, and when the non-DoD institution's IRB conducts the primary review. In accordance with both policy documents, the HRPO review is NOT a second IRB review. The purpose of the review is limited to only ensuring compliance with DoD-specific requirements. It is conducted by an

HRPP staff member at the OUSD(P&R) institution who is not a member of the institution's IRB, except in cases when the HRPP staff member is an alternate member of the IRB.

For purposes of situational awareness by an OUSD(P&R) institution that is supporting a research activity that includes human subjects for which it is NOT a performance site, the DoDI 3216.02 and the OUSD(P&R) OI permit the institution to conduct an Administrative Review of study documents and the primary IRB approval memorandum. This review is NOT an ethical compliance review, and it is NOT a second IRB review. As with the HRPO reviews, Administrative Reviews are conducted by an HRPP staff member who is not a member of the OUSD(P&R) institution's IRB, except in cases when the HRPP staff member is an alternate member of the IRB. The OUSD(P&R) institution may, at its discretion, elect to provide the principal investigator with a memorandum acknowledging the supporting role of the OUSD(P&R) institution. The Administrative Review shall not delay initiation of research by more than a few days.

Further details regarding these reviews can be found in the OUSD(P&R), R2O2 Policy Guidance Document (PG-01-005) *Duplicate Reviews, Human Research Protection Official (HRPO) Reviews and Administrative Reviews*. All Policy Guidance Documents are available from OUSD(P&R) institutional HRPP staff members, R2O2 staff members and, when updated, at the R2O2 website. Requests for copies of policy-related documents can be directed to the general R2O2 email box at [R2O2@mail.mil](mailto:R2O2@mail.mil).

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