Office of the Under Secretary of Defense
for Personnel and Readiness
Research Regulatory Oversight Office

Policy Guidance

Duplicate Reviews, Human Research Protection Official Reviews and Administrative Reviews

PG-01-005

R2O2

SUBJECT: This Policy Guidance Document explains the requirements for Administrative Reviews of studies approved by a DoD Institutional Review Board (IRB) and Human Research Protection Official (HRPO) Review of studies approved by a non-DoD IRB in accordance with References (b) – (d). It also explains the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)) implementation of the requirement to eliminate duplicative reviews in the absence of justification as articulated in Enclosure 3, Section 1.c.(4) of Reference (b) and Section 16.2 of Reference (c).

References: See References in Enclosure 1.

Policy Guidance History:

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Changes: This version of the document updates the website address for the R2O2, and reflects the new name for the Component Designated Official's office. No other substantive changes were made to the previous version (1.0).

1. PURPOSE. Policy Guidance documents are promulgated by the Research Regulatory Oversight Office (R2O2) within the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)) to articulate how Department of Defense (DoD) policy will be implemented across OUSD(P&R) institutions. The intent of all implementation strategies is to ensure consistency within and among OUSD(P&R) institutions.

2. APPLICABILITY. This Policy Guidance document applies to all institutions within the OUSD(P&R) that conduct or support research involving human subjects as defined in References (a), (b) and (c). A list of all OUSD(P&R) institutions can be found on the R2O2

website (http://www.health.mil/Military-Health-Topics/Research-and-Innovation/Research-Oversight). This Policy Guidance document applies to human subjects research conducted at OUSD(P&R) institutions by DoD personnel, contractors and collaborators (including those covered by the OUSD(P&R) Assurance through an Individual Investigator Agreement). It also applies to DoD-supported research conducted at non-DoD institutions to the extent that DoD personnel or beneficiaries are among the volunteer human subjects.

3. POLICY. OUSD(P&R) institutions conducting or supporting research involving human subjects will operationalize the DoD policy promulgated in Reference (b) as described in Enclosure 3 of this Policy Guidance document.

4. RESPONSIBILITIES. See Responsibilities in Enclosure 2.

5. PROCEDURES. Each OUSD(P&R) institution has an obligation to establish policies and procedures that reduce duplicate reviews in accordance with the requirements in References (b) and (c), and to conduct Administrative Reviews in the circumstances described in Reference (b) and Section 16.3.(d) of Reference (c). In accordance with Section 19 of Reference (c), R2O2 has an obligation to review and approve institutional Human Research Protection Programs (HRPPs) and institutional Standard Operating Procedures (SOPs). R2O2 must review and approve significant changes to these documents prior to implementation as well (Section 19 of Reference (c)). The procedures outlined in Enclosure 3 of this Policy Guidance Document will ensure consistent implementation across OUSD(P&R) institutions of a program that is compliant with the standards set in References (a) – (d).

6. RELEASABILITY. **Cleared for public release.** This Policy Guidance document is available on the Internet at the R2O2 website (http://www.health.mil/Military-Health-Topics/Research-and-Innovation/Research-Oversight) and on the Electronic Research Management Oversight System (ERMOS) website.

7. EFFECTIVE DATE. This Policy Guidance Document:

a. Is effective on 23 March 2015

b. Will expire on 22 March 2018 if it hasn't been reissued or cancelled before this date.

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Enclosures
1. References
2. Responsibilities
3. Procedures

Glossary

TABLE OF CONTENTS

ENCLOSURE 1

REFERENCES

(a) Section 219 of Title 32 of the Code of Federal Regulations, "Protection of Human Subjects"
(b) DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research"
(c) Office of the Under Secretary of Defense for Personnel and Readiness, Research Regulatory Oversight Office, "Operating Instruction," September 30, 2014
(d) Sections 2.101 and 252.235-7004 of Title 48, Code of Federal Regulations, the "DFARS Clause"

ENCLOSURE 2

RESPONSIBILITIES

1. ASSISTANT SECRETARY OF DEFENSE FOR RESEARCH AND ENGINEERING (ASD(R&E)). The ASD(R&E):
   a. Establishes policy for the protection of human subjects and a framework for ensuring such protections are afforded human subjects of research within the DoD.
   b. Establishes requirements for ethical review of research involving human subjects that ensures compliance with Reference (a) and encourages reduced redundancy.

2. DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH READINESS POLICY AND OVERSIGHT (DASD(HRP&O)). The DASD(HRP&O):
   a. Serves as the Component Designated Official for Human Research Protection Programs within the OUSD(P&R).
   b. Establishes OUSD(P&R) policy regarding compliance with the standards set in Reference (b) that will be implemented in each of the OUSD(P&R) institutions.

3. DIRECTOR, RESEARCH REGULATORY OVERSIGHT OFFICE (R2O2). The Director, R2O2:
   a. Creates Policy Guidance Documents that provide information on how compliance programs will be implemented across OUSD(P&R) institutions.
   b. Coordinates with Human Research Protection Program (HRPP) personnel in each of the institutions to create and implement the Standard Operating Procedures (SOP) in a manner that ensures consistency across all OUSD(P&R) institutions.
   c. Conducts assistance visits or inspections at OUSD(P&R) institutions during local SOP implementation in order to ensure compliance with this Policy Guidance Document.
   d. Conducts periodic audits, including audits for cause, of OUSD(P&R) institutions for compliance with References (a) – (d), as well as with this Policy Guidance Document and institutional SOPs.

4. INSTITUTIONAL OFFICIAL (IO). The IO:
   a. Is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the terms of the Federal-wide Assurance and the DoD Assurance.
   b. Establishes institutional-level policies and instructions for implementation and operationalization of the requirements in References (a) and (b) in accordance with this Policy Guidance Document.
   c. Ensures resources are available to fully implement and operationalize the SOPs in this Policy Guidance Document.

5. OTHER OFFICIALS DELEGATED IO AUTHORITIES. The other officials who have been delegated authorities to act on behalf of the IO (this does not apply to the Chiefs, Division/Department of Clinical Investigations, Chiefs, Department of Research Program, Human Protection Administrators, Exemption Determination Officials, Human Research

Protection Officials or Institutional Review Board (IRB) Chairs described in Sections 6., 7., 8., 9., 10. and 11. of Enclosure 2 of this Policy Guidance Document, respectively):

a. Executes those authorities as described in a "delegation of authorities" memorandum signed by the IO that details which authorities have been delegated, the duration of the delegation, any limitations or restrictions on the authorities so delegated, and a statement that no further delegation is permitted.
b. Establishes institution-level policies and instructions for implementation and operationalization of the requirements in Reference (b) in accordance with this Policy Guidance Document and reports, as necessary, to the IO (if delegated this authority by the IO).

6. CHIEF, DEPARTMENT OF RESEARCH PROGRAMS (DRP). The Chief, DRP:
   a. Creates SOPs for the implementation of programs at their respective OUSD(P&R) institutions that will ensure compliance with the requirements in References (a) – (d), and with this Policy Guidance Document. The Director, R2O2 will review and approve these SOPs before implementation. This function may be delegated to the Human Protection Administrator (HPA).

7. HUMAN PROTECTION ADMINISTRATOR (HPA). The HPA:
   a. Creates SOPs for the implementation of programs at their respective OUSD(P&R) institutions that will ensure compliance with the requirements in References (a), (b) and (c), and with this Policy Guidance Document. The Director, R2O2 will review and approve these SOPs before implementation.
   b. Monitors compliance with References (b) and (c), and this Policy Guidance Document among personnel within their respective institutions who are associated with the oversight of non-exempt research protocols involving human subjects. Provides guidance to those who are not compliant with Reference (b) – (d), and this Policy Guidance Document on steps to take to become compliant.

8. EXEMPT DETERMINATION OFFICIAL (EDO). The EDO:
   a. Creates SOPs for the implementation of programs at their respective OUSD(P&R) institutions that will ensure compliance with the requirements in References (a), (b) and (c), and with this Policy Guidance Document. The Director, R2O2 will review and approve these SOPs before implementation. This function may be delegated to the Human Protection Administrator (HPA).
   b. Monitors compliance with References (b) – (d), and this Policy Guidance Document among personnel within their respective institutions who are associated with the oversight of non-exempt research protocols involving human subjects. Provides guidance to those who are not compliant with Reference (b) – (d), and this Policy Guidance Document on steps to take to become compliant.

9. HUMAN RESEARCH PROTECTION OFFICIAL (HRPO). The HRPO:
   a. Creates SOPs for the review of research protocols that have previously been reviewed and approved by non-DoD IRBs in accordance with Reference (d). This function may be delegated to the Human Protection Administrator (HPA).

b. Monitors compliance with References (b) – (d), and this Policy Guidance Document among personnel within their respective institutions who are associated with the oversight of non-exempt research protocols involving human subjects. Provides guidance to those who are not compliant with Reference (b) – (d), and this Policy Guidance Document on steps to take to become compliant.
c. Conducts HRPO reviews of DoD-supported studies that are conducted under contract (or other funding/agreement mechanism) to a non-DoD vendor and/or approved by a non-DoD IRB in accordance with the requirements of Reference (d).

10. INSTITUTIONAL REVIEW BOARD (IRB) CHAIRS. The IRB Chairs:
    a. Conducts ethical reviews for compliance with requirements found in References (a)-(d) only when required as described in this Policy Guidance Document.

11. PRINCIPAL INVESTIGATORS (PI). The PI:
    a. Provides all required documentation for reviews in accordance with the requirements described in this Policy Guidance Document to the appropriate HRPP staff member or IRB Chair as described in institutional SOPs.

ENCLOSURE 3

PROCEDURES

1. DUPLICATE REVIEWS OF STUDIES
   a. Purpose. The DoDI 3216.02 (Reference (b)) and the OUSD(P&R) Operating Instruction (Reference (c)) each provides for reducing redundancy by requiring justification for multiple reviews of research studies that include human subjects. The OUSD(P&R) requirement is for written justification. The OUSD(P&R) implementation of those requirements is described herein.

      (1) Policy on Duplicate Reviews. References (b) and (c) seek to reduce redundant reviews that add little or no value to the mission of protecting human subjects. When a research study is reviewed and approved by a DoD IRB, Enclosure 3, Section 1.c.(4) of Reference (b), and Sections 13.2.g. and 16.2 of Reference (c) require one "to justify the duplication of reviews of protocols" with Reference (c) requiring that the justification be in writing. The R2O2 implementation of these requirements is:
      (a) there will be only one DoD-IRB review (expedited or full-board) without written approval from the Director, R2O2 (or designee) in advance of the review;
      (b) the IRB of record will be responsible for oversight and lifecycle actions, as well as inquiries into allegations of non-compliance, unanticipated problems involving risk to subject or others (UPIRTSO), adverse events, *etc.*;
      (c) Institutional Agreements for IRB Review (IAIR) will formalize the relationships between institutions;
      (d) written requests for exception to this policy must be submitted to and approval obtained by the Director, R2O2 (or designee) prior to any duplicate review conducted by an OUSD(P&R) institution;
      (e) all requests must be submitted electronically to dha.ncr.reg-support.mbx.r2o2@mail.mil using the template found at page 11 of this Policy Guidance Document, and must include strong justification for the exception to policy; and,
      (f) requests will be considered by R2O2 on a case-by-case basis. No OUSD(P&R) institution will be granted a blanket waiver of Sections 13.2.g. and Section 16.2 of the OUSD(P&R) Operating Instruction (Reference (c)).

2. HUMAN RESEARCH PROTECTION OFFICIAL (HRPO) REVIEWS
   a. Purpose. To ensure that protocols adequately address and fully comply with DoD-specific requirements for the protection of human subjects, the DoDI 3216.02 provides for HRPO and "HRPO-like" reviews when studies are initially approved by a non-DoD IRB (Enclosure 3, Section 4 of Reference (b)). This requirement is established in OUSD(P&R) policy at Section 17 of Reference (c).

(1) Policy on HRPO and "HRPO-like" Reviews. In accordance with Enclosure 3, Section 3.a.(8) of Reference (b) and Section 16.3 of Reference (c), OUSD(P&R) institutions may rely upon a non-DoD IRB for primary review and oversight if the enumerated conditions are met. The determinations made by non-DoD IRBs shall be subject to a HRPO or "HRPO-like" review by an OUSD(P&R) institution HRPP staff member for compliance with DoD-specific requirements that go beyond the protections provided by Section 219 of Reference (a). This is NOT a second IRB review. *Note:* the term "HRPO-like" review is used in this Policy Guidance Document in reference to an identical secondary review to the HRPO review; however, in the case of the former, the agreement between the non-DoD institution and the OUSD(P&R) institution is not a contract. "HRPO review" is a term that is codified in Reference (d) when the agreement is executed through a contract. The R2O2 implementation of these requirements is:

(a) these reviews shall be restricted to ensuring compliance with DoD-specific requirements and shall NOT be a second IRB review;

(b) these reviews include a review of all documents submitted to the primary IRB for review, the IRB determination memorandum and any additional DoD-specific documentation provided by the investigators, solely for the purpose of ensuring compliance with DoD-specific requirements. OUSD(P&R) institutions shall NOT require or request investigators to transfer information to the OUSD(P&R) institution's protocol templates. Instead, the OUSD(P&R) institution will review the protocol submitted to the primary IRB;

(b) these reviews shall be conducted by a member of the OUSD(P&R) institution's HRPP staff and NOT by an IRB member (except in the case when an HRPP staff member is an alternate member of the institution's IRB);

(c) these reviews shall also ensure:
(i) the collaborating non-DoD institution has an appropriate Federal Assurance;
(ii) DoD involvement is secondary to that of the non-DoD institution;
(iii) a written agreement between the two institutions is in place (*e.g.,* an IAIR);

(d) the product of these reviews shall be a "concurrence", "non-concurrence" or "concurrence with modifications required in order to comply with DoD-specific requirements" that is documented in a memorandum or letter to the Principal Investigator. Terms that are equivalent to "concurrence", "non-concurrence" or "concurrence with modifications required in order to comply with DoD-specific requirements" may be used by institutions provided the intent is the same.

3. ADMINISTRATIVE REVIEWS AS INDICATED OR NECESSARY

a. Purpose. DoDI 3216.02 (Reference (b)) and the OUSD(P&R) Operating Instruction (Reference (c)) provide for Administrative Reviews of studies when an OUSD(P&R) institution is "supporting" the specific activity. In these instances, the OUSD(P&R) institution is NOT a performance site, but is providing material support to the study (*e.g.,* funding, facilities, equipment, personnel, access to or information about DoD personnel for recruitment, or identifiable information or specimens from living individuals). This is NOT an ethical review. Instead, it is a "paperwork check" to ensure proper and complete documentation of the study and the institution's support has been submitted by study personnel, including personnel who are not affiliated with/employed by the OUSD(P&R)

institution. Administrative Reviews shall NOT delay initiation of research that has been reviewed and approved by a DoD IRB by more than five business days.

(1) Policy on Administrative Reviews as Indicated or Necessary. Administrative Reviews are conducted by non-IRB members of the OUSD(P&R) institution's HRPP staff (except in the case when an HRPP staff member is an alternate member of the institution's IRB) of studies reviewed and approved by a DoD IRB for the purpose of ensuring that all required documents are included in the study package. This review provides the OUSD(P&R) institution with the situational awareness of its role in the study.
   (a) The Administrative Review will include a review of the primary IRB's determination memorandum, the totality of documents submitted to the primary DoD IRB for review and any additional documents that may be required by the OUSD(P&R) institution (this should be rare).
   (b) An acknowledgement memorandum from the OUSD(P&R) institution's HRPP may be issued, or acknowledgement of the action in the Electronic Research Management Oversight System (ERMOS) will be made to formally acknowledge the review.

APPENDIX

Request for Exception to Policy to Conduct Duplicate IRB Review

Section 1: Institution and Study Information	
Requesting Institution:	Primary IRB:
Study Title:	Study ID:
Principal Investigator:	Primary Performance Site:
Is Requesting Institution a Performance Site?	Nature of Engagement:

Section 2: Category of Request for Exception
You must provide written supporting statement for each category selected
☐ The title of the study conveys a risk level that does not appear to match the IRB's determination
Supporting Statement:
☐ Concern about Conflict of Interest
Supporting Statement:
☐ History of lower than acceptable quality of service
Supporting Statement:
☐ Greater than minimal risk study at which the requesting institution is a performance site AND local context is critical
Supporting Statement:
☐ Other
Supporting Statement:

Section 3: Requesting Institution Submission	
HRPP Staff Member:	Date:

Section 4: R2O2 Action		
R2O2 Action:	☐ Approve	☐ Disapprove
R2O2 Staff Member		Date:
R2O2 Comments:		

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ASD(R&E)	Assistant Secretary of Defense for Research and Engineering
CFR	Code of Federal Regulation
DASD(HRP&O)	Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight
DCI	Department or Division of Clinical Investigation
DRP	Department of Research Programs
EDO	Exemption Determination Official
ERMOS	Electronic Research Management Oversight System
HPA	Human Protections Administrator
HRPO	Human Research Protection Official
HRPP	Human Research Protection Program
IAIR	Institutional Agreement for IRB Review
IO	Institutional Official
IRB	Institutional Review Board
OUSD(P&R)	Office of the Under Secretary of Defense for Personnel and Readiness
R2O2	Research Regulatory Oversight Office
SOP	Standard Operating Procedure
UPIRTSO	Unanticipated Problem Involving Risk to Subject or Others

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purpose of this Policy Guidance Document. Many terms defined in References (a), (b) and/or (c) are not repeated here.

Administrative Review. A review of a research protocol and supporting documents (*e.g.*, safety review, scientific review, IRB minutes) related to DoD-supported research involving human subjects which ensures the institution engaged in the research involving human subjects has met the requirements of all applicable regulations and policies. This review is NOT an IRB review.

Component Designated Official. The senior official within the OUSD(P&R) who has been delegated the authority for regulatory oversight of all human subjects research within the Component. For OUSD(P&R), that official is the DASD(FHP&R).

DoD-Supported Research. Research involving human subjects for which the DoD 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.

Duplicate Review. A second IRB review (either expedited or full-board) of a study that has already been reviewed and approved by another IRB, either a DoD IRB or a non-DoD IRB.

EDO. An official within an OUSD(P&R) institution, sufficiently qualified through training and experience, to determine if protocols 1) meet the regulatory definition of research, 2) include human subjects as defined in References (b) and (c) and 3) qualify for an exemption from IRB review in accordance with Section 101(b) of Part 219 of Title 32 Code of Federal Regulations.

Engaged. An institution is engaged when its personnel are conducting activities covered by Section 219.101(a) of Reference (a), DoDI 3216.02 (Reference (b)), the OUSD(P&R) Operating Instruction (Reference (c)) and this Policy Guidance Document. An institution that is funding, providing equipment or providing access to or information about potential human subjects (but not recruiting subjects), providing data or specimens (either identifiable or not), or overseeing the research from a regulatory or compliance standpoint is not engaged (but is supporting the research).

HPA. An official within an OUSD(P&R) institution who, for the purposes of HRPP matters, may communicate directly with the IO, and is responsible for the daily management of the institution's HRPP.

HRPO. An individual who is delegated the responsibility as defined in paragraph (a)(2) of section 252.235-7004 of Reference (d).

HRPO Review. Review required by Parts 207, 235 and 252 Title 48 of the Code of Federal Regulation ("DFARS Clause") to ensure DoD-specific requirements are met when a study is reviewed by a non-DoD IRB and the study is supported by a contract.

HRPO-Like Review. Same review as the HRPO review, except it is conducted when something other than a contract is used to support the study.