



**Office of the Under Secretary of Defense
(Personnel and Readiness)**

Research Regulatory Oversight Office

Human Research Protection Program

Operating Instruction

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1. INTRODUCTION

The Office of the Under Secretary of Defense for Personnel and Readiness (OUSDP&R)) ensures that all activities related to research involving human subjects, as defined in Part 219 of Title 32, Code of Federal Regulations (CFR), are guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," (the "Belmont Report") and in compliance with all applicable Federal statutes, regulations and Department of Defense Directives (DoDD) and Instructions (DoDI). The OUSDP&R) Research Regulatory Oversight Office (R2O2) oversees this process.

2. PURPOSE

This Operating Instruction (OI) describes how the OUSDP&R) R2O2 will implement and comply with 32 CFR 219 (reference a); Part 46 of Title 45, Code of Federal Regulations (45 CFR 46), subparts B, C, and D, as described in DoDD 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research;" DoD Directive 3216.02 (DoDD 3216.02) (reference b); Section 980 of Title 10, United States Code, (10 U.S.C. 980) (reference c); HA Policy 05-003, USD(P&R) Policy for Protection of Human Subjects in DoD-Sponsored Research, (reference d); and the OUSDP&R) Management Plan for the Human Research Protection Program (reference e).

3. APPLICABILITY AND SCOPE

This OI applies to all research involving human subjects, as defined by 32 CFR 219 and DoDD 3216.02, and all other activities that involve such research even in part, regardless of whether the research is otherwise subject to federal regulation, if:

- a. The research is supported (e.g., contract or grant) by the OUSDP&R), or
- b. The research is conducted under the direction of any employee or agent of the OUSDP&R), or
- c. The research is conducted using any property or facility of the OUSDP&R).

This OI applies to the OUSDP&R) in its entirety, to include its Field Activities and Organizations, and is not restricted by budget activity, program title, or funding source. This OI is *not* applicable to any entity outside the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness (USD (P&R)).

4. AUTHORITY AND DELEGATION

The USD(P&R), as the head of a DoD Component, has delegated the authority in DoDD 3216.02, paragraph 5.3, to the Assistant Secretary of Defense for Health Affairs (ASD(HA)) (reference k) who has further delegated that authority to the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness (DASD(FHP&R)) (reference l), hereafter referred to as the Component Designated Official (CDO).

Authorities and responsibilities within the OUSD(P&R) R2O2 are assigned as described in reference e.

4.1 Component Designated Official (CDO)/Human Research Protection Official (HRPO)

The authorities and responsibilities of the CDO and HRPO include, but are not limited to, the following:

- a. Responsibility for promoting efficient and effective policies for the OUSD(P&R) Human Research Protection Program (HRPP).
 - i. Authority to approve policies and procedures for the HRPP.
- b. Responsibility for promoting policies and procedures that are consistent with other components under the Office of the Secretary of Defense (OSD), including the Service Components.
 - i. Authority to represent the OUSD(P&R) HRPP on the Coordinating Committee for Human Subjects Research Protection or other committees formed by the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)).
- c. Responsibility for ensuring OUSD(P&R) institutions comply with applicable HRPP rules, regulations, and policies (references a – e).
 - i. Authority to approve Assurances for OUSD(P&R) institutions.
 - ii. Authority to approve appointments of individuals to serve as institution level HRPP managers and grant Exemption Determination Officials (EDOs) and Secondary Review Officials (SROs) with the authorities and responsibilities described in section 4.3.
 - iii. Authority to approve OUSD(P&R) granted addenda to the Federal Wide Assurance.
 - iv. Authority to approve program reviews and quality improvement activities.
 - v. Authority to adjudicate allegations of serious or continuing noncompliance involving OUSD(P&R) institutions and to determine when such allegations will be forwarded to another office for resolution (e.g., OSD, the Office of the Inspector General, or ASD(R&E))
 - vi. Authority to suspend or terminate OUSD(P&R) Assurances if in his judgment, the assured institution has displayed a significant or sustained pattern of disregard for mandated protection of human subjects of research as defined in reference f.
- d. Responsibility for ensuring OUSD(P&R) institutions comply with applicable sections of the Defense Federal Acquisition Regulation (DFAR) (reference g).
 - i. Authority to execute the requirements of the DFAR clause.
 - ii. Authority to stop payment on a contract if the research is out of compliance.
- e. Responsibility for ensuring OUSD(P&R) institutions comply with applicable research integrity and misconduct rules, regulations, and policies (reference f).
 - i. Authority to adjudicate allegations of research misconduct involving intramural or extramural human subjects research conducted or supported

by OUSD(P&R) institutions and to determine when such allegations will be forwarded to another office for resolution (e.g., the OSD, the Office of the Inspector General, or ASD(R&E)).

- f. Responsibility for ensuring sufficient personnel and resources to facilitate efficient and effective headquarters level operations of the OUSD(P&R) Research Regulatory Oversight Office (R2O2).
- g. Responsibility for ensuring appropriate education and training of personnel who participate in OUSD(P&R) HRPP and human subjects research activities.

4.2 R2O2 Component Program Manager

The authorities and responsibilities of the R2O2 Component Program Manager include, but are not limited to, the following:

- a. Responsibility for the routine management of the CDO's Headquarters HRPP Office (HQ) and the R2O2.
 - i. Authority to develop procedures to implement policies for the OUSD(P&R) HRPP.
 - ii. Authority to approve routine forms and agreements that do not establish new policy or commit the government to an expenditure of funds.
 - iii. Authority to approve routine Memoranda of Agreement and Understanding regarding joint review that do not establish new policy or commit the government to an expenditure of funds.
 - iv. Authority to conduct program reviews and quality improvement activities.
 - v. Authority to investigate allegations of noncompliance or research misconduct and assure resolution at the appropriate level.
 - vi. Authority to implement and monitor education and training requirements.
- b. Responsibility for maintaining records of component-level actions and activities as required by law and regulation.

4.3 Institution Level Officials

The following authorities and responsibilities may be vested in one or more individuals at the institution level. The assignment of authorities and responsibilities is documented in delegation memos, and with the concurrence of the CDO/HRPO.

4.3.1 Assured Institution Human Research Protection Program Manager

Each institution engaged in research which is covered by the regulation at reference a, and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in the regulation. An assured USD(P&R) institution conducts non-exempt human subjects research and must have a DoD issued Assurance. An assured institution's HRPP manager is appointed by the institution's Institutional Official and concurred upon by the CDO/HRPO. These individuals undergo an extensive training process during which time their authorities are strictly limited and they are subject to

constant oversight by the HQ. Once they have completed training and are fully qualified, then they are subject to review by the HQ as described in section 6 of this document. The HRPP manager has the authorities and responsibilities, which include, but are not limited to, the following:

- a. Responsibility for routine management of the Institutional Official's (IO's) human research protection program.
 - i. Authority to develop procedures to implement policies for the institution's HRPP.
 - ii. Authority to conduct program reviews and quality improvement activities.
 - iii. Authority to review reports of allegations of noncompliance or research misconduct, assure resolution at the appropriate level, and report as required, or in accordance with institutional policy.
 - iv. Authority to implement and monitor education and training requirements.
- b. Responsibility for maintaining records of all determinations and activities.
- c. Responsibility for providing updates to the IO as requested, but not less than annually.

4.3.2 Non-Assured Institution Designated Action Officer

A non-assured institution does not need the assurance document referenced in section 4.4.1 as a non-assured institution only conducts research that is exempt from the regulation at reference a, or supports research conducted by an assured institution. A non-assured institution's designated action officer (DAO) is appointed by an individual at the institution with the authority to sign on behalf of the institution, and concurred upon by the CDO/HRPO. The DAO has the authorities and responsibilities, which include, but are not limited to, the following:

- a. Responsibility for being aware of research activities within their institution and forwarding them to an EDO or SRO for determination as necessary.
 - i. Authority to develop procedures to ensure that contract officers and others at their institution are aware of the requirements.
- b. Responsibility for tracking all research activities forwarded to an EDO or SRO for determination.

4.3.3 Exemption Determination Official

- a. Responsibility for conducting timely and effective reviews of research.
 - i. Authority to determine whether an activity meets the regulatory definition of research involving human subjects.
 - ii. Authority to determine whether research involving human subjects qualifies for exemption from Institutional Review Board (IRB) review.
 - iii. Authority to establish and secure institutional agreements for IRB review (reference q).
- b. Responsibility for maintaining records of all determinations and activities.

- c. Responsibility for providing guidance regarding additional oversight, review, and approval requirements that may be needed prior to execution of the research.

4.3.4 Secondary Review Official

- a. Responsibility for conducting timely and effective review of research as required under the DFAR and research grants, as applicable.
 - i. Authority to conduct HRPO reviews.
 - ii. Authority to accept the official notification to the DoD by the institution receiving DoD support certifying that research involving human subjects has been approved by the IRB in accordance with the Assurance as required by the DFAR or grant.
 - iii. Authority to conduct second level reviews of non-exempt research involving human subjects.
 - iv. Authority to determine whether research protocols involving human subjects comply with all DoD requirements.
- b. Responsibility for maintaining records of all determinations and activities.
- c. Responsibility for providing guidance regarding additional oversight, review, and approval requirements that may be needed prior to execution of the research.

4.4 Institutional Official, IRB, and Researchers

a. Assured Institutions.

The IO, the IRB, and the researchers have the authorities and responsibilities described in references (a, b, and n). Some IO responsibilities may be delegated with concurrence of the CDO.

b. Non-Assured Institution.

The IO at a non-assured institution is responsible for being aware of research activities within the institution and for keeping the DAO informed of such activities. The IO also ensures the DAO has adequate support and authority to carry out the duties of the position, and serves as the point of contact in the event of research related problems.

5. POLICIES

5.1 Assurances of Compliance

a. Assurances of compliance for OUSD(P&R) institutions.

- i. OUSD(P&R) institutions engaged in non-exempt human subjects research must have a DoD Assurance approved by the Component Designated Official (CDO). The OUSD(P&R) uses the DoD Addendum to the FWA (reference p) as the template for such Assurances. Institutions must

submit to the CDO, written policies and procedures appropriate to the research conducted at the institution.

- ii. OUSD(P&R) institutions that only engage in exempt human subjects research or support research (e.g., via grant or contract) are not required to have a DoD Assurance; however, they must have a process in place for evaluating human subjects research activities to ensure they meet criteria for exemption under the regulations, or for conducting Human Research Protection Official reviews. The process must include review and concurrence by an HRPP Manager with the authorities and responsibilities of either an EDO or an SRO depending of the nature of the activity.
- iii. The process must be approved by the CDO.

b. Assurances of compliance for institutions engaged in research with OUSD(P&R) institutions.

- i. Institutions that are or become engaged in non-exempt human subjects research with an OUSD(P&R) institution must have a Federal Assurance of Compliance. DoD institutions must have a DoD assurance, non-federal institutions must have a Federal Wide Assurance (FWA) issued by the Department of Health and Human Services (HHS) Office for Human Research Protections, and federal institutions must have either an FWA or other Federal Assurance.

c. Assurances of compliance for individuals engaged in research with OUSD(P&R) Institutions.

- i. Individuals who are not affiliated with an institution holding a federally approved assurance of compliance (e.g., individuals in private practice or independent on-site contractors) and who wish to engage in non-exempt human subjects research with an OUSD(P&R) institution, either through collaboration or sponsorship, may be added to the OUSD(P&R) institution's assurance by entering into an Individual Investigator Agreement. The agreement must be formalized using reference o, and approved by the IO. The IO should ensure that there is a monitoring plan commensurate with the volume and risk-level of the research.

d. Acceptance of Assurances from institutions outside the OUSD(P&R)

- i. Unless the research qualifies for exemption, OUSD(P&R) institutions may only engage in human subjects research with other federally-assured institutions. In the case of international research, OUSD(P&R) institutions may engage in research with foreign institutions as long as those institutions have policies and procedures for ethical review and oversight of research that is equivalent to our federal requirements as determined by the ASD(R&E).
- ii. OUSD(P&R) CDO will accept all DoD Assurances without further review provided the terms of the assurance cover the proposed research.
- iii. If the OUSD(P&R) is only engaged in the research as a sponsor and is not engaged in the conduct of the research, the OUSD(P&R) CDO will accept

an HHS assurance in conjunction with a DoD Addendum to the FWA (reference p) in which the HHS assured institution agrees to follow DoD unique and the OUSD(P&R) institution's specific requirements. The addendum must be approved by the CDO.

- iv. If the OUSD(P&R) institution is engaged in the conduct of the research but not primarily responsible for the conduct of the research, the Institutional Agreement for IRB Review (IAIR) may be used between the engaged institutions (federal and non-federal) to place responsibility for the required reviews onto a single IRB. The IAIR must be approved by the Institutional Officials of both institutions and forwarded to HQ as an attachment to the assurance.

e. Renewal and Revision of OUSD(P&R) Approved Assurances.

To keep an existing OUSD(P&R) Assurance active or current, a renewal must be approved by the CDO every three years. If the nature or scope of the Assurance changes or if there is a significant change in policies and procedures, the Assurance must be renegotiated. Routine agreements (e.g., Institutional Agreement for IRB Review, Individual Investigator Agreements) and activities (rotation of IRB members) become addenda to the institution's Assurance. The R2O2 must be notified of all agreements and revisions.

f. Suspension of OUSD(P&R) Issued Assurances.

The CDO has the authority to suspend or revoke OUSD(P&R) Assurances or OUSD(P&R) acceptance of federal Assurances from other institutions. Any such suspensions will be reported immediately to ASD(R&E).

5.2 Component Oversight of Assurance Granting Authority

The R2O2 will:

- a. Review requests for an Assurance from OUSD(P&R) institutions and ensure signatories to the Assurance have training in their authorities and responsibilities under the Assurance before signing and periodically thereafter.
- b. Review DoD Addenda (reference p) to ensure non-OUSD(P&R) institutions and individuals understand their authorities and responsibilities under an OUSD(P&R) accepted Assurance.
- c. Review submitted IRB membership roster to ensure it is appropriate for the research.
- d. Maintain a list of currently approved and accepted Assurances.
- e. Conduct routine quality assurance activities to ensure program effectiveness.

5.3 Research Review and Oversight

The CDO ensures that the R2O2 and OUSD(P&R) duly recognized and appointed reviewers will provide due diligence in oversight of research conducted by institutions within the OUSD(P&R), conducted by institutions having an assurance approved by the OUSD(P&R), or supported by the OUSD(P&R).

Intramural research protocols and research-like activities are reviewed as follows. Institutionally based EDOs are responsible for determining whether research-like activities meet the regulatory definition of research involving human subjects and, if so, whether the research qualifies for exemption under 32 CFR 219. Non-exempt human subjects research is reviewed by an IRB identified on the institution's Assurance document or addendum.

An OUSD(P&R) institution may rely upon the review and oversight by a DoD IRB with approval of both institutions that is formalized using the DoD Institutional Agreement for IRB Review (reference q), or by using a Memorandum of Agreement (MOA). The MOA is appropriate for designating a DoD IRB as the IRB of record for the OUSD(P&R) institution; otherwise, the IAIR is the preferred agreement for specific protocols.

An OUSD(P&R) institution may rely upon the review and oversight by a federal, non-DoD IRB with approval of both institutions as long as DoD personnel are not anticipated to constitute more than half of the subject pool.

An OUSD(P&R) institution may rely upon the review and oversight by a non-federal, non-DoD IRB with approval of both institutions as long as ALL of the following conditions apply:

1. The DoD is not the predominant party in the cooperative research project. Predominance is measured in relation to overall responsibility for the conduct of the study.
2. The research does not require an IRB to make a determination that prior consent may be provided by a legal representative of the subject because the subject lacks capacity (due to age, condition, or other reason) to provide informed consent, or that this requirement may be waived as described in 10 USC 980.
3. Subsequent to IRB approval, the responsible official of the DoD Component makes a determination that all other requirements of DoDD 3216.02 and 32 CFR Part 219 are met. This focuses on DoD-specific requirements, as well as Part 219 procedures for institutional Assurances.

Sponsored research protocols and research-like activities are reviewed by the grant or contract recipient's institution and the outcome is forwarded to the SRO for HRPO review and approval/acceptance.

The SRO is responsible for the determinations identified in item 3 above. Institutional approval is documented using the IAIR (reference q). SRO responsibilities may be deferred to another DoD component upon mutual agreement, which may be documented using a MOA with the appropriate oversight office within that component. Headquarters-level review should be sought for research that is particularly sensitive, politically charged, or that involves foreign nationals.

6. INSTITUTIONAL OVERSIGHT

The R2O2 monitors the accountability of institutions and IRBs conducting and approving research under an Assurance approved by the USD(P&R), and non-assured institutions operating under an HRPP plan. HRPP's, SROs and EDOs under the purview of the USD(P&R) are subject to formal review approximately every three years or as needed in the event of reasonable cause for concern. Formal reviews will be announced by memo from the CDO to the IO. Reports of findings from the formal review will be sent from the CDO to the IO. If the findings include deficiencies, then R2O2 may include an action plan to address the deficiencies in the memo. Before the findings memo is sent to the IO, the R2O2 will send the draft memo to the SRO/EDO and other appropriate institutional representatives for comment and review. The amount of time given to the institutional representatives for review will be determined by the length and nature of the findings, will be stated in the cover note and generally will not exceed 10 business days. Any substantive comments received from the institutional representatives that are not accepted by R2O2 will be included as an attachment in the memo from the CDO to the IO. The IO may direct appeals regarding the findings or action plans to the CDO.

HQ also conducts periodic assistance visits and informal reviews of OUSD(P&R) institutions to provide guidance and assistance where needed. R2O2 initiates most of these reviews; however, the SRO/EDO may request an informal review if desired. At the conclusion of an informal review, a summary of R2O2's findings is sent only to the SRO/EDO unless s/he requests a copy be sent to the IO or supervisor. If deficiencies are found during routine informal reviews, R2O2 may suggest an action plan to address the deficiencies. If the deficiencies are significant, then the findings and action plan will be forwarded to the IO from the CDO. In general, R2O2 will strive to conduct assistance visits and informal reviews of institutions prior to any routine formal review.

6.1 Scope of Oversight

The scope of HQ oversight includes the following:

1. Institutional policies and procedures for implementing references (a)-(g) in Appendix A;
2. Institutional policies and procedures for implementing the scientific review requirements established in the DoD Assurance of Compliance;
3. Institutional policies and procedures for implementing the education and training requirements established in reference (d) in Appendix A and Section 8 below.

6.2 USUHS Infectious Disease IRB HQ Panel

In addition to the reviews described above, the Infectious Diseases IRB at the Uniformed Services University of the Health Sciences has a Joint Service-USD(P&R) oversight panel (reference r) that conducts administrative reviews of all research that is international, greater than minimal risk, or Food and Drug Administration (FDA) regulated. The panel must concur with the IRB determination before the research may commence.

6.3 Resolving Conflicts between Multiple Reviews

If an OUSD(P&R) reviewer does not concur with another review group's determination, and the non-concur would result in a higher level review than suggested by the primary reviewer or IRB or would result in a disapproval of the protocol, then the protocol will be sent to the R2O2 for determination. The R2O2 will make a determination and follow-up as needed with the responsible parties.

6.4 Secondary Review

In the event that an EDO/SRO is unavailable to conduct a secondary review, the default is that another EDO/SRO will conduct the review. However, in extraordinary circumstances, HQ can conduct these reviews.

7. OTHER HQ REVIEWS

7.1 Report Control Symbol Review Process

The OUSD(P&R) must review and approve any survey requiring participation of personnel in any DoD Component, other than the supporting Component before it may be submitted to the Director, Washington Headquarters Service (WHS) in accordance with DoDI 8910.01, "Information Collection and Reporting," and DoDI 1100.13, "Surveys of DoD Personnel." The Defense Manpower Data Center (DMDC), shall review and recommend approval of such survey requests to the OUSD(P&R). Upon receipt of DMDC's recommendation, R2O2 reviews the survey and forwards its determination to the DoD Clearance Officer at WHS. For OUSD(P&R) purposes, this requirement does not apply to investigator-initiated research which is not intended to inform policy. Sponsoring Federal agencies (e.g., PHS) that fund surveys of the general public or members of the DoD may have their own specific review and clearance requirements.

7.2 OSD Sponsor Reviews

When non-DoD entities request OSD sponsorship in order to comply with Privacy Act and other requirements, HQ assists these entities by reviewing their proposals and determining their sponsorship eligibility.

8. HRPP TRAINING

Institutions under the purview of the USD(P&R) have a triennial Collaborative Institutional Training Initiative (CITI) training requirement for all individuals engaged in HRPP activities, including conducting, reviewing and overseeing research involving human subjects. For P&R-supported research activities, this requirement applies to the PI and other individuals with a significant role in the research. If the PI has already completed training to satisfy an institutional requirement, the PI may submit documentation of that training to the HRPP program manager, who will determine if the training is equivalent to the P&R required training.

In addition, all personnel involved in the program, including CDO, Oversight Office staff, IOs, IRB members, Administrative staff, and investigators must complete interim training to be eligible to participate in activities under the purview of the HRPP. These activities include the support, review or conduct of research involving humans.

8.1 Training Requirements

- a. Initial Training: Completion of the initial human research protections training is required prior to any work on a human research protocol. The Initial Training is completed through the Collaborative Institutional Training Initiative (CITI) and is valid for three years.
- b. Interim Training: All active research personnel are required to participate in additional continuing education opportunities. All personnel must complete four hours of research-ethics continuing training. This training should be completed no sooner than one year, and no later than two years following completion of initial training.
- c. Triennial Training: Every three (3) years, all research personnel must become re-certified in human subjects' protection training. The CITI on-line human subjects' protection training program satisfies this requirement (as described above).

8.2 Training of Institutional Officials (IOs)

Institutional Officials and other institutional executives have the option of receiving a personal briefing by the R2O2 in lieu of the training described above. IOs must have training prior to signing an Assurance.

8.3 Training Tracking

The R2O2 maintains an electronic training file for individuals involved in human subject research activities with OUSD(P&R) institutions. The file tracks completion of the three year training requirement, not the training completed in the off-years. R2O2 sends notification emails to trainees 30 days prior to expiration of their training.

9. COMMUNICATION

The CDO ensures that they, or their designee, will keep ASD(R&E), or designee, informed of significant issues regarding the safety of human subjects, including the following:

1. any suspension or termination of an Assurance;
2. any investigation of the OUSD(P&R) conducted by an outside entity;
3. any investigation of a grantee by the OUSD(P&R) or other federal entity for allegations covered by this management plan that results in negative findings.

10. CLASSIFIED RESEARCH

In the event an OUSD(P&R) institution proposes to engage in classified research, R2O2 will convene an ad hoc IRB consisting of current members from existing DoD IRBs to review the proposed research. Expedited review procedures shall not be used to review classified research. The ad hoc IRB will consist of at least five members with appropriate clearance levels, including one non-governmental member. All non-exempt classified research must be approved by the Secretary of Defense prior to initiation. Protocols are submitted to the Secretary by the ASD(R&E) via the CDO.

Exempt classified research must be approved by the CDO or by the individual designated by the CDO with preference given to a political appointee with senate confirmation such as an ASD. This determination is made on a case by case basis and depends on the potential political implications.

11. CONFLICT OF INTEREST

The CDO ensures that he, or his designee, provide an environment that identifies and strive to reduce the possibility for conflict of interest by personnel responsible for protecting human subjects. The OUSD(P&R) R2O2 has established procedures for identifying and addressing conflicts of interest (COI) issues. Institutions have procedures for identifying COI, and protocols with COI that cannot be addressed at the institutional level are forwarded to the R2O2 for review or resolution.

11.1 Definition

A COI is a situation in which someone in a position of trust, such as a research scientist or physician, has competing professional or personal or financial interests. A conflict of interest exists even if no unethical or improper act results. The following procedures will be used to manage potential conflicts of interest.

11.2 EDO or SRO Reviewer COI

If an EDO or SRO has a COI with a protocol, then the EDO/SRO should forward the protocol to another OUSD(P&R) EDO/SRO. The second EDO/SRO will review the protocol and inform the initial reviewer of the determination.

If an IRB member or Chair has a COI with a protocol, then the member or Chair may not participate in the IRB's initial or continuing review of that project except to provide information requested by the IRB.

11.3 R2O2 Reviewer COI

If the R2O2 has a COI with a protocol, then the R2O2 will forward the protocol to another DoD HRPP headquarters office or IRB for review.

11.4 Financial COI

OUSD(P&R) institutions must have procedures in place for identifying and mitigating financial conflicts of interest related to research, and they must be included in their written standard operating procedures.

12. RESEARCH RELATED UNANTICIPATED PROBLEMS AND UNANTICIPATED SERIOUS ADVERSE EVENTS

12.1 Research-Related Unanticipated Problems

The HRPP Program Manager will report all research-related unanticipated problems and unanticipated serious adverse events to the R2O2 HQ within one business day of verifying the problem and include a recommendation on how to address the problem or a description of steps already taken. The R2O2 HQ will then determine whether to concur with the recommendations or actions taken. If R2O2 does not concur, the CDO may choose to require further action.

12.2 Research Related Injury

12.2.1 Regulatory Background

The Common Rule requires that research subjects involved in greater than minimal risk research be informed of the availability of medical treatment or compensation if a research-related injury occurs. This information should inform the subject if treatment is available, and if it is, what that consists of or where further information may be obtained (32 CFR 219.116(6)). In addition, DoDD3216.02 requires DoD Components to protect research subjects from medical expenses (not otherwise provided or reimbursed) that are the direct result of participation in a research project involving greater than minimal risk.

12.2.2 Secretarial Designee Status

For greater than minimal risk studies, participants will be limited to DoD beneficiaries except in the following conditions:

- (1) Potential participants are eligible for DoD secretarial designation status in accordance with reference h, or
- (2) There is an indemnification policy, or similar, protecting potential participants from any research related medical expenses.

Determination of beneficiary status should be verified using the Defense Enrollment Eligibility Reporting System.

12.3 Suspension or Termination of Approval

In the event of a decision to suspend or terminate approval of a study for cause, the HRPP Program Manager will document and report the decision to the IRB (if applicable) and R2O2 within one business day and follow-up with a detailed report within three business days.

13. EXTRAMURAL CONTRACT LANGUAGE

The CDO is also the HRPO and is responsible for oversight and execution of the requirements of the DFAR Supplement (reference g).

14. DOCUMENTATION AND RECORD KEEPING

As specified in the OUSD(P&R) R2O2 records disposition plan, paper and electronic records relating to research will be retained for ten years after completion of the research. Inquiries about P&R oversight activities should be directed to the R2O2 Program Manager as the record owner.

For the studies that it reviews, the HRPP Program Managers should maintain the following documentation:

- a. A copy of the determination and the notification given to the Principal Investigator;
- b. Copies of all information used to make the decision with contact information for the PI, descriptions of the PI's affiliations and qualifications, description of the research setting and research purpose, description of research procedures and subject selection, information and informed consent documents given to subjects, questionnaires and similar documents to include inclusion of individual subject personal information, and other documentation as appropriate.
- c. Copies of notifications and rationales for deciding an activity does not fit the regulatory definition of human subject research where the rationale could be questioned by reasonable people.

15. SIGNATURE APPROVAL

As the CDO for the OUSD(P&R) HRPP, I hereby approve this Operating Instruction.

Signature  Date 17 June 2011
Dr. George Peach Taylor
Deputy Assistant Secretary of Defense
(Force Health Protection and Readiness)

16. APPENDIX A (References)

- (a) 32 CFR 219, "Protection of Human Subjects," current edition
- (b) DoDD 3216.02, "Protection of Human Subjects in DoD-Supported Research," March 25, 2002
- (c) 10 USC 980, "Limitations on Humans as Experimental Subjects"
- (d) HA Policy 05-003, "USD(P&R) Policy for Protection of Human Subjects in DoD-Sponsored Research," March 28, 2005
- (e) USD(P&R) Management Plan for the Human Research Protection Program
- (f) DoDI 3210.7, "Research Integrity and Misconduct," May 14, 2004
- (g) 48 CFR 207, 235, and 252, "Defense Federal Acquisition Regulation Supplement; Protection of Human Subjects in Research Projects," July 29, 2009
- (h) 32 CFR 108, "Health Care Eligibility Under the Secretarial Designee Program and Related Special Authorities," December 27, 2010
- (i) DoDI 8910.01, "Information Collection and Reporting," March 6, 2007
- (j) DoDI 1100.13, "Surveys of Department of Defense Personnel," November 21, 1996
- (k) USD(P&R) memorandum, "Delegation of Human Research Subjects Protection Authority," August 11, 2008
- (l) ASD (HA) memorandum, "Delegation of Human Research Subjects Protection Authority," August 26, 2008
- (m) DASD (FHP&R) memorandum, "Department of Defense-wide Human Subject Research Protection Assurances," September 7, 2007
- (n) OUSD(P&R) version of the DoD-wide Assurance Template
- (o) DoD Individual Investigator Agreement Template
- (p) DoD Addendum to the Federal Wide Assurance (FWA) Template
- (q) DoD Institutional Agreement for IRB Review (IAIR)
- (r) ASD (HA) memorandum, "Memorandum of Understanding (MOU) of Uniformed Services University of Health Sciences (USUHS) Infectious Disease Clinical Research Program (IDCRP) Review Panel and Institutional Review Board for Infectious Disease Research Protocols," October 19, 2007