



Office of the Under Secretary of Defense
for Personnel and Readiness (OUSD[P&R])
Research Regulatory Oversight Office

Policy Guidance
OUSD(P&R) Institutional Training Requirements
(Human Research Protection Program)

PG-03-001

R2O2

SUBJECT: This Policy Guidance document explains the requirements for role-based training in human research protections at Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)) institutions.

References: See References in Enclosure 1.

Policy Guidance History:

Document Number	Document Version	Effective Date	Lifecycle Review Date	Signature
PG-03-001	1.0	01NOV2014	31OCT2017	
PG-03-001	1.1	24 June 2015	31 October 2017	ECKERT.JOHN.J. 1248350624

Changes: This version of the document updates the email address and new 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://home.fhpr.osd.mil/resources/research-regulatory-oversight/rroo_mission.aspx). This Policy Guidance document applies to human subjects research conducted at OUSD(P&R) institutions by DoD personnel, contractors, 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. The DoD-specific requirements must be met through non-DoD institutional training supplemented by successful completion of training on DoD-specific requirements.

3. **POLICY**. OUSD(P&R) institutions conducting or supporting research involving human subjects will operationalize the DoD policy promulgated in Reference (a) 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 affirmative obligation to ensure that personnel associated with research protocols involving human subjects have access to and receive the appropriate role-based training as described in Reference (a). The R2O2 has the affirmative obligation to ensure that the training program is available to personnel at all OUSD(P&R) institutions and that the training is up-to-date with current Federal regulations and DoD-wide policies. 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 Reference (a).

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 and Oversight System (ERMOS) website.

7. **EFFECTIVE DATE**. This Policy Guidance Document:

- a. Is effective on 01 NOV 2014.
- b. Will expire effective 31 OCT 2017 if it hasn't been reissued or cancelled before this date.

ECKERT.JOHN.
J.1248350624

Digitally signed by
ECKERT.JOHN.J.1248350624
DN: c=US, o=U.S. Government,
ou=DoD, ou=PKI, ou=USPHS,
cn=ECKERT.JOHN.J.1248350624
Date: 2015.06.24 17:02:52 -04'00'

CAPT John J. Eckert, PhD, CIP
Acting Director, R2O2

Enclosures

1. References
2. Responsibilities
3. Procedures

Glossary

TABLE OF CONTENTS

ENCLOSURE 1: REFERENCES.....4

ENCLOSURE 2: RESPONSIBILITIES.....5

 ASSISTANT SECRETARY OF DEFENSE FOR RESEARCH AND ENGINEERING
 (ASD(R&E)).....5

 DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH READINESS
 POLICY AND OVERSIGHT (DASD(HRP&O)).....5

 DIRECTOR, RESEARCH REGULATORY OVERSIGHT OFFICE (R2O2).....5

 INSTITUTIONAL OFFICIAL (IO)5

 OTHER OFFICIALS DELEGATED IO AUTHORITIES.....6

 CHIEF, DIVISION/DEPARTMENT OF CLINICAL INVESTIGATION (DCI)6

 CHIEF, DEPARTMENT OF RESEARCH PROGRAMS (DRP).....7

 HUMAN PROTECTION ADMINISTRATOR (HPA).....7

 EXEMPT DETERMINATION OFFICIAL (EDO).....7

 HUMAN RESEARCH PROTECTION OFFICIAL (HRPO)8

 INSTITUTIONAL REVIEW BOARD (IRB) CHAIR.....8

 PRINCIPAL INVESTIGATOR (PI)8

 ASSOCIATE INVESTIGATORS (AI) AND OTHER RESEARCH TEAM MEMBERS9

 RESEARCH SUPPORT PERSONNEL, RESEARCH MONITORS (RM)9

 RESEARCH SUBJECTS9

ENCLOSURE 3: PROCEDURES10

 MINIMUM EDUCATION REQUIREMENTS FRAMEWORK (MERF) STANDARDS....10

 Role-Based Training10

 Guidance on Role-Based Training.....10

 HRPP TRAINING10

 Training Requirements.....10

 Training of Institutional Officials12

 Training Tracking12

 Lapses in Training.....12

 RECIPROCITY13

 Reciprocity.....13

 Exceptions to Reciprocity13

 APPENDIX

 MERF in OUSD(P&R) Institutions14

GLOSSARY15

 PART I: ABBREVIATIONS AND ACRONYMS15

 PART II: DEFINITIONS.....16

ENCLOSURE 1

REFERENCES

- (a) Directive Type Memorandum, “Minimum Education Requirements for DoD Personnel Involved in Human Research Protection,” August 16, 2012
- (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

ENCLOSURE 2

RESPONSIBILITIES

1. ASSISTANT SECRETARY OF DEFENSE FOR RESEARCH AND ENGINEERING (ASD(R&E)). The ASD(R&E):

- a. Establishes a framework for educational training requirements for DoD personnel in key roles of a DoD human research protection program in accordance with section 1.f of Enclosure 2 of Reference (b).

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. Ensures role-based training programs are available and up-to-date.
- c. 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.
- d. Exercises approval authority for implementing SOPs at OUSD(P&R) institutions related to training requirements for individuals associated with research protocols involving human subjects.
- e. Conducts assistance visits or inspections at OUSD(P&R) institutions during local SOP implementation in order to ensure compliance with this Policy Guidance document.
- f. Conducts periodic audits, including audits for cause, of OUSD(P&R) institutions for compliance with References (a), (b) and (c), as well as with this Policy Guidance document and institutional SOPs.
- g. Maintains current training in human research protections as required by Reference (a).

4. INSTITUTIONAL OFFICIAL (IO). The IO:

- a. Is legally authorized to act for the institution and, on behalf of the institutions, 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 Reference (a) in accordance with this Policy Guidance document.
- c. Ensures resources are available to fully implement and operationalize the SOPs in Section 4.a. of this Policy Guidance document.

- d. Completes IO specific training in the protection of human subjects in research as described in Section 2.b. of Enclosure 3 of this Policy Guidance document. That training may be provided by the Director, R2O2, institutional HRPP Program Manager or through online courses that have been developed and approved by the Director, R2O2.
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. Execute 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 permitted.
 - b. Establishes institution-level policies and instructions for implementation and operationalization of the requirements in Reference (a) in accordance with this Policy Guidance document and reports, as necessary, to the IO (if delegated this authority by the IO).
 - c. Completes IO specific training in the protection of human subjects in research as described in Section 2.b. of Enclosure 3 of this Policy Guidance document. That training may be provided by the Director, R2O2, institutional Human Protection Administrator or through online courses that have been developed and approved by the Director, R2O2.
 - d. These officials are not permitted to execute the authorities delegated to them by their respective IOs until documentation of successful completion of training requirements has been received by the Director, R2O2.
 - e. Maintains current training in human research protections as required by Reference (a).
6. CHIEF, DIVISION/DEPARTMENT OF CLINICAL INVESTIGATION (DCI). The Chiefs, DCI:
- a. Provides documentation of successful completion of training requirements as described in Reference (a) to the Director, R2O2.
 - b. Creates SOPs for the implementation of programs at their respective OUSD(P&R) institutions that will ensure compliance with the requirements in Reference (a) and this Policy Guidance document. These SOPs will be reviewed and approved by the Director, R2O2 before execution. This function may be delegated to the Human Protection Administrator (HPA).
 - c. Monitors compliance with Reference (a) and this Policy Guidance document among personnel within their respective institutions who are associated with research protocols involving human subjects. Provides guidance to those who are not compliant with Reference (a) and this Policy Guidance document on steps to take to become compliant. Delegable to HPA.
 - d. Provides guidance and advice (oral and written) on steps individuals who are associated with research protocols involving human subjects must take to achieve and maintain compliance with the requirements in Reference (a), this Policy Guidance document and their institutional SOPs. This function may be delegated to the HPA.

- e. Maintains current training in human research protections as required by Reference (a).
7. CHIEF, DEPARTMENT OF RESEARCH PROGRAMS (DRP). The Chief, DRP:
- a. Provides documentation of successful completion of training requirements as described in Reference (a) to the Director, R2O2.
 - b. Creates SOPs for the implementation of programs at his/her OUSD(P&R) institution that will ensure compliance with the requirements in Reference (a) and this Policy Guidance document. These SOPs will be reviewed and approved by the Director, R2O2 before execution. This function may be delegated to the HPA.
 - c. Monitors compliance with Reference (a) and this Policy Guidance document among personnel within his/her institution who are associated with research protocols involving human subjects. Provides guidance to those who are not compliant with Reference (a) and this Policy Guidance document on steps to take to become compliant. Delegable to HPA.
 - d. Provides guidance and advice (orally and in written format) on steps individuals associated with research protocols involving human subjects must take to achieve and maintain compliance with the requirements in Reference (a), this Policy Guidance document and the institutional SOPs. This function may be delegated to the HPA.
 - e. Maintains current training in human research protections as required by Reference (a).
8. HUMAN PROTECTION ADMINISTRATOR (HPA). The HPA:
- a. Provides documentation of successful completion of training requirements as described in Reference (a) to the Director, R2O2.
 - b. Creates SOPs for the implementation of programs at their respective OUSD(P&R) institutions that will ensure compliance with the requirements in Reference (a) and this Policy Guidance document. These SOPs will be reviewed and approved by the Director, R2O2 before execution.
 - c. Monitors compliance with Reference (a) and this Policy Guidance document among personnel within their respective institutions who are associated with research protocols involving human subjects. Provides guidance to those who are not compliant with Reference (a) and this Policy Guidance document on steps to take to become compliant.
 - d. Provides guidance and advice (orally and in written format) on steps individuals who are associated with research protocols involving human subjects must take to achieve and maintain compliance with the requirements in Reference (a), this Policy Guidance document and their respective institutional SOPs.
 - e. Maintains current training in human research protections as required by Reference (a).
9. EXEMPT DETERMINATION OFFICIAL (EDO). The EDO:
- a. Provides documentation of successful completion of training requirements as described in Reference (a) to the Director, R2O2.
 - b. Creates SOPs for the implementation of programs at their respective OUSD(P&R) institutions that will ensure compliance with the requirements in Reference (a) and this Policy Guidance document (within institutions without Director, HRPP, Chief, DCI, Chief, DRP or HPA). These SOPs will be reviewed and approved by the Director, R2O2 before execution.

- c. Monitors compliance with Reference (a) and this Policy Guidance document among personnel within their respective institutions who are associated with research protocols involving human subjects (within institutions without Chief, DCI, Chief, DRP, HPA). Provides guidance to those who are not compliant with Reference (a) and this Policy Guidance document on steps to take to become compliant.
 - d. Provides guidance and advice (orally and in written format) on steps individuals who are associated with research protocols involving human subjects must take to achieve and maintain compliance with the requirements in Reference (a), this Policy Guidance document and their respective institutional SOPs (within institutions without Director, HRPP, Chief, DCI, Chief, DRP or HPA).
 - e. Maintains current training in human research protections as required by Reference (a).
10. HUMAN RESEARCH PROTECTION OFFICIAL (HRPO). The HRPO:
- a. Provides documentation of successful completion of training requirements as described in Reference (a) to the Director, R2O2.
 - b. Creates SOPs for the implementation of programs at their respective OUSD(P&R) institutions that will ensure compliance with the requirements in Reference (a) and this Policy Guidance document (within institutions without Director, HRPP, Chief, DCI, Chief, DRP or HPA). These SOPs will be reviewed and approved by the Director, R2O2 before execution.
 - c. Monitors compliance with Reference (a) and this Policy Guidance document among personnel within their respective institutions who are associated with research protocols involving human subjects (within institutions without Director, HRPP, Chief, DCI, Chief, DRP or HPA). Provides guidance to those who are not compliant with Reference (a) and this Policy Guidance document on steps to take to become compliant.
 - d. Provides guidance and advice (orally and in written format) on steps individuals who are associated with research protocols involving human subjects must take to achieve and maintain compliance with the requirements in Reference (a), this Policy Guidance document and their respective institutional SOPs (within institutions without Director, HRPP, Chief, DCI, Chief, DRP or HPA).
 - e. Maintains current training in human research protections as required by Reference (a).
11. INSTITUTIONAL REVIEW BOARD (IRB) CHAIR. The IRB Chairs:
- a. Provides documentation of successful completion of training requirements as described in Reference (a) to the Chief, DRP, Chief, DCI or Director, HRPP.
 - b. Reviews protocol submission packages to ensure that participants involved in the conduct of research activities that include human subjects have completed the training commensurate with their roles on the studies as required in Reference (a) and this Policy Guidance document. When deficiencies are found, the IRB shall notify the Principal Investigators (PI) of those deficiencies prior to granting full approval of the studies.
 - c. Maintains current training in human research protections as required by Reference (a).
12. PRINCIPAL INVESTIGATOR (PI). The PI:
- a. Provides documentation of successful completion of training requirements as described in Reference (a) to the IRB as part of each protocol submission package.

- b. Ensures each member of the research team has successfully completed the training for his/her role on the study as described in Reference (a).
- c. Restricts members of the research team from participating in the study until documentation of successful completion of the training for his/her role on the study as described in Reference (a) is provided to the PI.
- d. Maintains current training in human research protections as required by Reference (a).

13. ASSOCIATE INVESTIGATORS (AI) AND OTHER RESEARCH TEAM MEMBERS.

The AI and other research team members:

- a. Provide documentation of successful completion of training requirements as described in Reference (a) to the PI and IRB as part of each protocol submission package.
- b. Maintains current training in human research protections as required by Reference (a).

14. RESEARCH SUPPORT PERSONNEL, RESEARCH MONITORS (RM). The Research Support Personnel and RM:

- a. Provide documentation of successful completion of training requirements as described in Reference (a) to the PI and IRB as part of each protocol submission package.
- b. Maintains current training in human research protections as required by Reference (a).

15. RESEARCH SUBJECTS. The Research Subjects:

- a. May, if they choose, complete training as described in Reference (a); however, there is no requirement for them to do so.
- b. Retain certificates of completion or completion reports as part of their research records.

ENCLOSURE 3PROCEDURES1. MINIMUM EDUCATION REQUIREMENTS FRAMEWORK (MERF) STANDARDS

a. Purpose. The MERF (Reference (a)) provides the foundation for role-based training requirements as required in Section 5 of Enclosure 3 of Reference (b). The OUSD(P&R) implementation of those requirements is described herein.

(1) Role-Based Training. The MERF (Reference (a)) defines ten (10) Categories of Roles in the DoD HRPPs (Learner Groups). For each Learner Group, the MERF lists competencies that shall be included in the training program. The OUSD(P&R) has refined the Learner Groups and mapped the competencies to specific training modules that are available through the Collaborative Institutional Training Initiative (CITI). The Learner Groups for OUSD(P&R) institutions are:

- (a) Senior DoD Component Leadership and Institutional Officials
- (b) DoD Component Headquarters (HQ) Oversight Personnel
- (c) Institutional Review Board Members and IRB Support Staff
- (d) Advisors to the Institutional Official
- (e) Biomedical Investigators and Research Study Team
- (f) Social and Behavioral Investigators and Research Study Team
- (g) Research Support Personnel
- (h) Research Monitors, Ombudsman, Subject Advocates and Data Safety Monitoring Boards (DSMB)
- (i) Regulatory Oversight of Extramural Human Subjects Research
- (j) Research Subjects

(2) Guidance on Role-Based Training. Guidance to individuals associated with research protocols involving human subjects regarding the Learner Group they should affiliate with to satisfy the role-based training requirements in Reference (a) will be provided by the institutional HRPP staff members. A representative sample of some functions related to each of the 10 Learner Groups is presented in the Appendix to this Policy Guidance document. The list is not comprehensive.

2. HRPP TRAINING

a. Training Requirements.

(1) Initial Training. All personnel associated with research protocols that involve human subjects are required to complete initial human subjects protection training prior to any work on a human research protocol. The initial training is completed through the CITI program and is valid for three years.

- (a) Individuals will be required to enroll in CITI training and successfully complete the modules associated with the roles they will assume with the research activities on which they will participate. Successful completion is defined as

- achieving at least 80% correct responses on the assessment questions across all required modules, collectively.
- (b) Individuals must complete the requisite CITI training for each role that they will assume on research activities that involve human subjects. That is, if an individual serves on multiple human research protocols and has a different role on each of them, then that individual must complete the CITI training modules for each role. The CITI program includes logic that recognizes modules that have already been completed by an individual and will only assign modules that are required for a particular role that have not already been completed by the individual within the past three years.
- (2) **Interim Training.** Each institution is responsible for providing opportunities for, and keeping record of interim research ethics continuing training for its individuals associated with research protocols involving human subjects in accordance with Reference (a).
- (a) Interim training should be completed no sooner than one year and no later than two years following completion of initial training.
- (b) Latitude should be granted by the institutional HRPP staff members when accepting activities that satisfy the interim training requirement. Attendance at professional conferences, reading books or peer-reviewed publications on ethics in human subjects research, completion of additional online training in human research protection-related topic areas, *etc.* should all be considered as satisfying this requirement.
- (c) Documentation of at least four (4) hours of interim training within the three year period for which the CITI training completion is valid shall be maintained as described in Section 2.c. of Enclosure 3 of this Policy Guidance document.
- (3) **Triennial Training.** Every three (3) years, all personnel associated with research protocols involving human subjects must become recertified in human subjects protection training in accordance with Reference (a). The CITI online human subjects protection training program tailored to the specific role of the individuals satisfies this requirement.
- (a) Individuals may complete the full curriculum for the specific roles they will assume on each project with which they are associated, or
- (b) When available, individuals may elect to complete the “Refresher Training” curriculum to satisfy this requirement.
1. Under some circumstances, the institutional HRPP managers may require the full curriculum on case-by-case basis (for cause) or as the standard practice at the institution.
- (c) Individual research team members will be responsible for tracking their own training expiration dates and ensuring that there are no lapses in training during the course of each study with which they are associated. The PI for each study is responsible for ensuring that all members of the research team have completed, and maintain currency of role-based training requirements at the time of protocol submission and throughout the course of the studies with which they are associated as the PI.

- (d) Lapses in training currency will be subject to the sanctions noted in Section 3.d. of Enclosure 3 of this Policy Guidance document.
- (e) Obtaining and maintaining accreditation as a “Certified IRB Professional” (CIP) from the Council for Certification of IRB Professionals will satisfy this requirement. Information on CIP certification is available from institutional HRPP managers and R2O2.

b. Training of Institutional Officials.

- (1) IO Training. Institutional Officials and other institutional executives (including Other Officials Delegated IO Authorities) have the option of receiving a personal briefing by the R2O2 in lieu of the training described in Reference (a) and in Section 2.a. of Enclosure 3 of this Policy Guidance document.
 - (a) IO Training should be completed before the IO assumes the responsibilities outlined in Section 4 of Enclosure 2 of this Policy Guidance document. Instances may arise that necessitate assumption of responsibilities before IO training is complete. In such instances, the IO training must be completed within 3 months of assumption of those responsibilities.
 - (b) IO Training must be completed before the IO signs the institution’s Assurance.
 - (c) Even when an IO delegates responsibilities and authorities of the IO to other officials within the institution, he/she must still receive IO training in accordance with Reference (a).

c. Training Tracking. The R2O2 maintains an electronic training file for individuals involved in human subjects research activities with OUSD(P&R) institutions. The file tracks completion of the initial and triennial training requirements. R2O2 sends notification email messages to trainees 30 days prior to expiration of their initial and triennial training. Institutions are encouraged to maintain training tracking files. The ERMOS should include training tracking functionality.

- d. Lapses in Training. On occasion, individuals associated with research protocols involving human subjects may experience lapses in the currency of their training. Depending upon the role of the individual whose training currency lapses, the sanctions shall be calibrated to the potential impact of such a lapse on the rights and welfare of the subjects. The Chief, DCI, Chief, DRP, HPA or other official within the institution with authority over the human research protection program, in concert with the IRB:
 - (1) May temporarily suspend research activities on a study for which the Principal Investigator (PI) is not compliant with Reference (a) and this Policy Guidance document. Follow all guidance regarding suspension of studies such that risk to human subjects is not impacted through abrupt cessation of intervention.
 - (2) May allow research activities to continue on a study for which a member of the study team, not identified as the PI, is not compliant with Reference (a) and this Policy Guidance document. Individuals who are not the PI and are not compliant as described above, may be barred from participating in any research activities until they provide documentation of successful completion of training requirements as described in this Policy Guidance document.

3. RECIPROCITY

- a. **Reciprocity**. Each institution within the OUSD(P&R) will accept as satisfying the training requirements in Reference (a) from any and all individuals who have successfully completed the appropriate role-based training curriculum offered by CITI and managed by the R2O2.
- b. **Exceptions to Reciprocity**. An OUSD(P&R) institution may elect to not accept the training curriculum offered by CITI as satisfying the training requirements in Reference (a) if:
 - (1) the training was not in the role for which the individual will be serving on the specific protocol, AND if the modules completed previously do not include one or more of the required modules for the role for which the individual will be serving on the specific protocol, or
 - (2) the training completed was managed by a DoD Component HQ office other than R2O2 or a non-DoD institution (*e.g.*, academic institution, other Federal agency) AND the training modules do not meet the requirements in Reference (a). If, however, the training modules completed by the individual are routinely accepted by institutions in the DoD Component or non-DoD institution that manages the training, then the OUSD(P&R) institutions should give weight to that when determining applicability and acceptability of the training, and require only those additional CITI modules that provide instruction on the DoD-specific requirements.

APPENDIX

MERF in OUSD(P&R) Institutions

Learner Groups

1. Senior DoD Component Leadership and Institutional Officials
 - a. CDO
 - b. IOs
2. DoD Component HQ Oversight Personnel
 - a. R2O2 staff members
3. Institutional Review Board Members and IRB Support Staff
 - a. IRB members
 - b. HRPP staff members
4. Advisors to the Institutional Official
 - a. HPAs
 - b. Chiefs of DCIs/DRP
 - c. Other key advisors to the IO on HRPP matters (*e.g.*, attorneys, those delegated authorities by the IO for HRPP functions, ethicists)
5. Biomedical Investigators and Research Study Team
 - a. PIs
 - b. AIs
 - c. Research Monitors
 - d. Study Coordinators
 - e. Personnel involved in administrative functions aligned with a study
 - f. Personnel obtaining informed consent
 - g. Individuals with access to PII (including PHI) for analytical purposes
6. Social and Behavioral Investigators and Research Study Team
 - a. PIs
 - b. AIs
 - c. Research Monitors
 - d. Study Coordinators
 - e. Personnel involved in administrative functions aligned with a study
 - f. Personnel obtaining informed consent
 - g. Individuals with access to PII (including PHI) for analytical purposes
7. Research Support Personnel
 - a. Personnel interacting or intervening with subjects for one portion of a study (*e.g.*, radiologist/radiology technician performing CT scans in support of a study, phlebotomist performing blood draws for all subjects in a study, *etc.*)
8. Research Monitors, Ombudsman, Subject Advocates & DSMBs
 - a. Self-explanatory
9. Regulatory Oversight of Extramural Human Subjects Research
 - a. HRPO
10. Research Subjects
 - a. Self-explanatory

GLOSSARYPART I. ABBREVIATIONS AND ACRONYMS

AI	Associate Investigator
ASD(R&E)	Assistant Secretary of Defense for Research and Engineering
CITI	Collaborative Institutional Training Initiative
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
DSMB	Data Safety Monitoring Board
EDO	Exemption Determination Official
ERMOS	Electronic Research Management and Oversight System
HPA	Human Protections Administrator
HQ	Headquarters
HRPP	Human Research Protection Program
IO	Institutional Official
IRB	Institutional Review Board
MERF	Minimum Education Requirements Framework
OUSD(P&R)	Office of the Under Secretary of Defense for Personnel and Readiness
PI	Principal Investigator
R2O2	Research Regulatory Oversight Office
SOP	Standard Operating Procedure

PART II. DEFINITIONS

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

Assistance visit. An onsite review of OUSD(P&R) institutional HRPP business processes, SOPs, records management, determinations for representative subset of protocols, resources supporting the HRPP, *etc.* either at the invitation of the institution, as required of R2O2 as described in Reference (c) or for cause, with the intent of identifying deficiencies as well as best practices as part of an overall process improvement program. Feedback is provided to the institution's HPA by the Director, R2O2. Follow-up visits are made within six months to ensure corrective actions have been taken.

Associated with research protocols involving human subjects. Any individual who is part of a research team, including ombudsmen, data analysts working with identifiable data, PI, AI, research coordinator, RM, or those involved with regulatory oversight of human subjects research.

Audit. A formal onsite review of OUSD(P&R) institutional HRPP business processes, SOPs, records management, determinations for representative subset of protocols, resources supporting the HRPP, IRB activities (if applicable), *etc.* either in support of the institution's Assurance renewal, for cause, or as part of an overall process improvement program. Feedback is provided to the institution's IO and HPA by the Director, R2O2. Follow-up visits are made within six months to ensure corrective actions have been taken.

CITI. A web-based service that provides role-based training in the ethical issues and regulatory compliance requirements with respect to human subjects research. The training has been tailored to meet the requirements outlined in Reference (a).

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(HRP&O).

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.

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.

MERF. As directed in Reference (b), the standards for role-based training of individuals associated with research protocols involving human subjects in the regulatory requirements and ethical principles protecting the rights and welfare of the volunteer subjects.