

Part II: DoD and OUSD(P&R) Specific and Unique requirements

References:

- (a) [32 CFR 219](#) – Protection of Human Subjects
- (b) [45 CFR 46](#) – Protection of Human Subjects, Department of Health and Human Services
- (c) [DoI Directive 3216.02](#) – Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research
- (d) [10 USC 980](#) – Limitations on use of humans as experimental subjects
- (e) [18 USC 209](#) – Salary of Government officials and employees payable only by United States
- (f) Health Affairs Policy and Guidance [96-050](#), Policy for Off-Duty Employment by DoD Health Care Practitioners, dated 7 July 1996
- (g) [5 CFR 2635.801](#), et seq., Standards of Conduct for Executive Branch, Subpart H, Outside Activities (employment)
- (h) Joint Ethics Regulation, [DoD 5500.7-R](#) paragraphs 2-206 and 2-303.
- (i) [24 USC 30](#) – Payments to donors of blood for persons undergoing treatment at Government expense
- (j) DoD Instruction [8910.01](#) – Information Collection and Reporting
- (k) DoD [8910.1-M](#) – Department of Defense Procedures for Management of Information Requirements
- (l) Public Law [104-13](#) – Paperwork Reduction Act of 1995
- (m) [5 USC 552a](#) – The Privacy Act of 1974, as amended
- (n) DoD Directive [5400.11](#) – DoD Privacy Program
- (o) [45 CFR Part 164](#) – Security and Privacy
- (p) DoD Instructions [6025.18](#) – Privacy of Individually Identifiable Health Information in DoD Health Care Programs
- (q) [DoD 6025.18-R](#) – DoD Health Information Privacy Regulation
- (r) DoD Instruction [1100.13](#) – Surveys of DoD Personnel
- (s) DoD Instruction [3210.7](#) – Research Integrity and Misconduct

1.0 DoD Human Subjects Regulations

1.1.0 The Common Rule

1.1.1 The human subjects regulation is called the “Common Rule” because 18 Federal departments and agencies have all adopted the **identical** regulation. The most frequently cited version of the Common Rule is 45 CFR 46 from the Department of Health and Human Services (DHHS) (reference b). However, DoD’s human subject regulation is 32 CFR 219 (reference a), and it is functionally equivalent to 45 CFR 46.

1.2.0 Applicability of the Subparts

1.2.1 The Common Rule is also known as Subpart A, and in the DHHS version of the rule it is followed by Subparts B-D which contains additional protections for vulnerable

populations. The DoD did not adopt Subparts B, C, and D as regulation; however, the Department did adopt the subparts through directive (reference c). Thus, Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research, Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, and Subpart D – Additional Protections for Children Involved as Subjects in Research all apply to DoD-sponsored or conducted research.

2.0 Assurances

2.1 The Department of Defense (DoD) has authorized a small number of officials to issue DoD assurances of compliance. The Under Secretary of Defense (Personnel and Readiness) is so authorized, and has delegated that authority to the Deputy Assistant Secretary of Defense (Force Health Protection and Readiness). OUSD(P&R) assurance numbers have the following designation: DoD-P600XX, where the “XX” represents a unique number assigned to the institution.

2.2 If an awardee institution or any of the collaborating sites does not have an Assurance, then they must obtain an Assurance before they may engage in the research. If the awardee institution or performance site is external to the DoD, then they should negotiate a Federal Wide Assurance with Office for Human Research Protections (OHRP) in DHHS. If the awardee or performance site is a DoD institution, then they should negotiate an Assurance with the appropriate DoD office. OUSD(P&R) institutions should contact the HRPP HQ for instructions and information regarding Assurances. For information regarding DHHS assurances, see www.hhs.gov/ohrp/assurances/assurances_index.html.

2.3 If a collaborating investigator is not an employee of an institution with a federal assurance, a DoD Individual Investigator Agreement (IIA) may be used to bring the investigator under the assurance of an assured institution for the purpose of conducting research indicated in the scope of the document. The IIA describes the responsibilities of the individual researcher who is engaged in human subject research and the responsibilities of the assured institution.

3.0 Informed Consent

3.1.0 10 United States Code 980 – Limitation on Use of humans as experimental subjects

3.1.1 The following is the full text of the statute (reference d):

"(a) Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless- (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject.

(b) The Secretary of Defense may waive the prohibition in this section with respect to a specific research project to advance the development of a medical product necessary to the armed forces if the research project may directly benefit the subject and is carried out in accordance with all other applicable laws."

3.2.0 DoD Instruction 3216.02 clarification of 10 USC 980

Reference c defines “research involving a human being as an experimental subject” as “an activity for research purposes, where there is **an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction.**” This does not include: treatment, practice, or compliance monitoring activities, or activities exempt under 32 CFR 219. Thus, 10 USC 980 does not apply to human subjects research that is exempt from the common rule or to most research using survey procedures or interview procedures.

3.3.0 Application of 10 USC 980

3.3.1 When 10 USC 980 is applicable, if an individual cannot give his or her own consent to participate in a research study, consent of the individual’s legally authorized representative must be obtained prior to the use of the individual as an experimental subject. Moreover, under 10 USC 980, an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, or minors) may not be enrolled as an experimental subject in DoD sponsored research unless the research is intended to benefit each subject enrolled in the study. For example, a subject may benefit directly from medical treatment or surveillance beyond the standard of care. Investigators should be aware that this law makes placebo controlled clinical trials problematic because of the ‘intent to benefit’ requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.

3.4.0 10 USC 980 and Survey Research

3.4.1 Exemption at 32 CFR 219.101(b)(2) does not apply to research involving children (see footnote in reference a for exceptions); however, children/minors may be enrolled in minimal risk research using educational tests or survey and interview procedures that are not intended to benefit each minor as long as the purpose of the research activity is **not** to obtain data regarding the effect of the intervention or interaction as defined in reference c and explained in 3.2.0. However, the IRB must ensure that adequate provisions are in place to solicit the assent of the minor and the permission of the parent as specified in Subpart D – Additional Protections for Children involved as subjects in Research (reference b).

4.0 Subject Recruitment

4.1.0 Chain of Command in Military Facilities

4.1.1 Generally a letter of support is needed from the Commander of military facilities or units in which recruitment will occur or the study will be conducted. This is considered necessary in order to conduct a study within that command. Some sites may also require that each volunteer seek written permission from his/her supervisor prior to participation in research studies. There may be additional service specific approvals required, and review by an IRB within the service may be required in addition to the PI’s institution.

4.1.2 The Chain of Command should not be involved in the recruitment of military personnel and should not encourage or order soldiers to participate in a research study. The letter of support from the Commander referenced in 4.1.1 should not be used as a recruiting tool with the military personnel.

4.2.0 Ombudsman

4.2.1 Special consideration must be given to the recruitment process for military personnel. In accordance with reference c, when research involves greater than minimal risk, an ombudsman must be employed when conducting group briefings with Active Duty personnel to ensure they understand that participation is voluntary. The use of an ombudsman may be recommended in other situations as well, especially when young enlisted soldiers are recruited who are trained to follow orders. For minimal risk research employing group briefings, an ombudsman may be employed if reasonably available. Soldiers are trained to act as a unit, so peer pressure should also be considered and minimized if possible.

5.0 Surveys and Data Requests

5.1.0 Survey Licensure

5.1.1 Under DoD Directive 8910.1 (reference (j)), surveys and other information collections conducted or sponsored by USD(P&R) institutions may require approval by the DoD Internal Reports Manager, who resides in Washington Headquarters Service (WHS) if subjects are recruited from more than one service component. Each military Service has its own internal approval process for collections of information involving only that one Service. Procedures for the review and approval of DoD internal information requirements are covered in Chapter 4 of DoD 8910.1-M (reference (k)). Contact your component's Information Management Control Officer (IMCO) for more information or assistance with the process.

5.1.2 OMB Approval

If the subject population includes members of the public, the information collection may also require approval by the Office of Management and Budget (OMB) in accordance with Paper Work Reduction Act requirements (reference (l)). Procedures for the review and approval of DoD public information requirements are covered in Chapter 3 of DoD 8910.1-M (reference (k)) Contact your component's Information Management Control Officer (IMCO) for more information or for assistance with the process.

5.2.0 Privacy Requirements for Data

5.2.1 The Federal Privacy Act (reference (m)) applies to all identifiable (e.g., name, address, SSN) data maintained within a DoD System of records. The collection, maintenance, use, and dissemination of such data are subject to the Privacy Act, as implemented by DoD Directive 5400.11 (reference (n)). Further, if the research involves protected health information (PHI), the Medical Privacy Rule to the Health Insurance Portability and Accountability Act (reference (o)), as implemented by the DoD Health Information Privacy Regulation (DoD 6025.18-R)(reference (q)), applies. This regulation requires that documentation of an alteration to or waiver, in whole or in part, of HIPAA Authorization for use or disclosure of PHI, in the case of research conducted or supported by a DoD Component, be approved by a properly constituted IRB or a privacy board established in accordance with 32 CFR 219.107. Requests for Military Health System (MHS) Data require negotiating a Data Use Agreement (DUA) with the TRICARE Management Activity (TMA) Privacy Office. For more information see www.tricare.osd.mil/tmaprivacy.

6.0 Compensation of Federal Employees Participating as Subjects in Research

6.1.0 Federal Subjects Paid Directly from a Federal Source

6.1.1 References (e-h) contain the guidance on the use of federal moneys to pay subjects of research but are not applicable to the use of non-federal monies.

Notwithstanding the source of the payment, some Federal employees, both uniformed and civilian are subject to certain restrictions or limitations on their ability to accept compensation. Any federal employee who has questions regarding their ability to accept compensation should be referred to the ethics counselor for their command or organization.

6.1.2 In accordance with reference (f), Department of Defense Graduate Students and Medical Residents are prohibited from engaging in off-duty employment and therefore may not be compensated for their participation in research.

6.1.3 During non-duty hours, many Federal employees (civilian and uniformed) may be compensated for participation in research studies. However, some may be prohibited from accepting compensation without explicit prior approval from their agency and others will be required to report their participation to their supervisors. Additionally, many agencies and commands require these requests to be reviewed by a standards-of-conduct official in addition to reviewing them for potential impact on readiness (References g and h).

6.1.4 It is possible to pay any DoD employee (civilian or military) \$50.00 per blood draw under (reference i) using federal or nonfederal monies.

6.2.0 Non- Federal Monies Used for Compensation

6.2.1 Cooperative and other studies which may involve non-federal participation and funding may change the dynamics of compensation. The limitations will not apply if the funding for the compensation is independent of any federal funding. Federal contracts for research should not dictate the terms or use of compensation for research subjects. However, remember that Federal employees are still required to obtain authorization to engage in off-duty employment as outlined in paragraph 6.1.3 above and in accordance with references g and h.

7.0 Uniform Code of Military Justice

7.1 Privacy and confidentiality risk assessment for military personnel requires serious consideration of the potential impact on a military career, as some medical and psychological diagnoses can lead to limitation of duties or discharge. Information regarding alcohol or drug abuse, drunk driving, sexual or spousal abuse and sexual orientation can lead to actions under the Uniform Code of Military Justice (See <http://www.constitution.org/mil/ucmj19970615.txt>, particularly Chapter X: Punitive Articles) including incarceration and dishonorable discharge. For aviators and submarine personnel, loosing flight/submarine qualified status or flight/submarine pay due to a physical or psychological concern is an issue.

8.0 Research Monitor

8.1 Per DoD Instruction 3216.02, all greater than minimal risk studies require a medical monitor. The name of the research monitor must be included in the protocol and curriculum vitae must be provided.

8.2 Research monitors shall be physicians, dentists, psychologists, nurses, or other healthcare providers capable of overseeing the progress of the research protocols, especially issues of individual subject/patient management and safety. Research monitors shall possess sufficient educational and professional experience to serve as the subject/patient advocate.

8.3 For greater than minimal risk research in which the primary risk to subjects is breach of confidentiality, then it may be desirable to have a qualified professional who is not a health care provider serve as the study monitor. For example, if the primary risk to subjects is breach of confidentiality and the study is web-based, then an IT security professional may be the most appropriate research monitor.

8.4 In the protocol, please note that the research monitor has the authority and ability under reference c to stop research, remove subjects from the protocol, or take whatever steps are deemed necessary to protect the safety or wellbeing of the subject(s) until the IRB can assess the situation and the medical monitor's report.

9.0 Reporting to the IRB and the Human Research Protection Program (HRPP) HQ

Note: IRB Approval Letters issued for DoD regulated research must include a risk level determination from the IRB.

9.1.0 Unanticipated Problems

9.1.1 The protocol must describe the procedures for reporting unanticipated problems that are: (1) unexpected, (2) related or possibly related to participation in the research or (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. Unanticipated problems should be reported to all IRBs at intervals required by each IRB. All unanticipated problems must be reported promptly to the HQ as well as to the IRBs. Internal P&R IRBs have procedures in place for notifying the HQ of unanticipated problems as well as reports of research misconduct; therefore, additional notifications are not required.

When an unanticipated problem is sent to HQ, if Office of Human Research Protection (OHRP) is supported or funded by another federal agency is involved, it may be necessary to notify them, as well.

9.2.0 Protocol Modifications

9.2.1 Include a statement in the protocol describing the procedures for protocol modifications. This should include approval by the local IRB prior to implementation of the modification and prompt notification of the HQ when the change is significant or when it adversely impacts the risk/benefit assessment for the study. Internal P&R IRBs have procedures in place for notifying the HQ; therefore, additional notifications are not required.

9.3.0 Protocol Deviations

9.3.1 Include a statement in the protocol describing the procedures for reporting deviations from the protocol. This should include the procedures for reporting deviations to the local IRB and to the HQ. Any deviations that fit the category of “unanticipated problems involving risks to volunteers or others” should be promptly reported. Internal P&R IRBs have procedures in place for notifying the HQ; therefore, additional notifications are not required.

10.0 Consent Process Special Information

10.1 When a P&R institution has primary responsibility for the research (or in other cases as appropriate), then potential subjects may be told during the informed consent process that they may report concerns regarding the research to the human research protection program (HRPP) HQ at hrpp@tma.osd.mil or to the institutional HRPP.

10.2.0 Review of Research Records

10.2.1 For research sponsored or conducted by a P&R institution, include a statement in the protocol and consent form that representatives of the Under Secretary of Defense (Personnel & Readiness) are authorized to review research records as part of their responsibility to protect human research volunteers. In the event that a HIPAA authorization is required, include the above as parties to whom private health information may be disclosed.

10.3.0 Medical Care for Research Related Injury

10.3.1 A research-related injury is any unfavorable medical occurrence in a human research subject that is unexpected, related to the subject’s participation in the research, and serious in nature. Greater than minimal risk research can not be approved unless there is a plan to protect participants from medical expenses that are the direct result of participating in the research. Thus, greater than minimal risk studies must meet one of the following:

1. Only recruit subjects from populations eligible for health care through DoD or TRICARE Management Activity;
2. Obtain an insurance policy for the potential participants which are approved by the IRB as being sufficient;
3. Obtain approval from the Component Designated Official for participants who may be injured in the study to be granted Secretarial Designee Status.

Any incident of research-related injury involving provision of health care will be reported to the IRB (if applicable), SRO, and HQ. The HRPP Component Program Manager will consult with general counsel regarding recommended actions.

10.3.2 In some circumstances, the IRB or Component Designated Official (CDO) may require the researchers to provide health insurance for the research subjects.

10.4.0 Mandatory Reporting Notification/Duty to Report

10.4.1 For military volunteers, the consent form must contain a notification when complete confidentiality cannot be guaranteed because information bearing on a service

member's health, Uniformed Code of Military Justice may be required to be reported to appropriate medical or command authorities.

11.0 Exemption Procedures

11.1 Certain categories of research are exempt from IRB review in accordance with Federal guidelines. Decisions regarding exemption may be made by IRBs, as outlined in their policies and procedures, or by OUSD(P&R) Exempt Determination Officials (EDOs), Secondary Review Officials (SROs) and Head Quarters. Determination decisions must be reported to the principal investigator in writing.

12.0 Secondary Review

12.1 In accordance with reference c, the Human Research Protection Program (HRPP) SRO or HQ conducts secondary review research involving human subjects as needed.

13.0 Training

13.1 Institutions under the purview of the Under Secretary of Defense (Personnel and Readiness) have a triennial Collaborative Institutional Training Initiative (CITI) training requirement for all individuals engaged in Human Research Protection Program (HRPP) activities, including conducting, reviewing and overseeing research involving human subjects. This includes research activities conducted via grant or contract.

P&R HRPP Web Site

The following website provides the latest information on policies, relevant references for P&R HRPP users:

[OUSD\(P&R\) Human Research Protection Program \(HRPP\)](#)