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

Department of Defense (DoD) Requirements

Information for researchers and IRBs regarding the regulations and requirements for human subjects research when OUSD(P&R) institutions are engaged in the research

References:

(a) 32 CFR 219 – Protection of Human Subjects
(b) 45 CFR Part 46 – Protection of Human Subjects, Department of Health and Human Services
(c) DoD 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 Directive 6025.18 – Privacy of Individuals Identifiable Health Information in DoD Health Care Programs

1.0 DoD Human Subjects Regulations

1.1.0 The Common Rule

1.1.1 The "Common Rule," found in Subpart A of 45 C.F.R. Part 46 has been adopted by 18 Federal departments. The promulgation of the Common Rule for the Department of Defense (DoD) is found in 32 C.F.R. Part 219.

1.2.0 Additional guidance

1.2.1 DoD Directive 3216.2 "Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research"

In addition to adopting the Common Rule, DoD has issued additional direction and guidance concerning human subjects research. DoD Directive 3216.2, reference (c), for all who do research within DoD or for research supported by DoD. Additionally the statutory requirements and policies provided in references (d) through (k) also apply.

1.2.2 10 United States Code 980 – Limitation on Use of humans as experimental subjects

This statute, reference (d) is applicable only within the DoD, thus persons outside of DoD should review the statue prior to engaging in human subjects research to determine its applicability to their projects. Note that pursuant to reference (c), paragraph E.2.1.3.4 activities exempt under the Common Rule are not included in the definition of research involving a human being as an experimental subject.

2.0 Assurances

2.1 DoD Assurances

2.1.1 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). USD(P&R) assurance numbers have the following designation: DoD-P600XX, where the "XX" represents a unique number assigned to the institution.

2.2 Other Assurances

2.2.1 If an awardee institution or any of the collaborating sites does not have an Assurance—either an "Assurance for the Protection of Human Research Subjects by a DoD Institution" or a Federal Wide Assurance (FWA) with the Department of Health and Human Services (DHHS), Office of Human Research Protection (OHRP)—then they must obtain an Assurance before they may be engaged in the research. For more information on obtaining a Federal Wide assurance see www.hhs.gov/ohrp/assurances/assurances_index.html

3.0 Subject Recruitment

3.1.0 Chain of Command in Military Facilities

3.1.1 Pursuant to reference (c), a letter of support from the Commander of military facilities or units in which recruitment will occur or the study will be conducted will be requested. Some sites may also require that each volunteer seek written permission from his/her supervisor prior to participation in research studies. Civilian investigators attempting to access military volunteer pools may wish to seek collaboration with an investigator who is familiar with service specific requirements.

3.2.0 Ombudsman

3.2.1 When recruiting a percentage of a unit as volunteers in a study with greater than minimal risk, special consideration must be given to the requirements of paragraph 4.4.4 of reference (c) regarding the appointment of an ombudsman.

4.0 Surveys and Data Requests

4.1.0 Survey Licensure

4.1.1 Under DoD Directive 8910.1 (reference (j)), surveys and other information collections conducted or sponsored by USD(P&R) institutions generally require approval by the DoD Internal Reports Manager, who resides in Washington Headquarters Service (WHS). Specifically, approval by the DoD Internal Reports Manager is required when DoD internal information collection involves more than one DoD component. For example, if a survey draws

subjects from two or more military Services, or if P&R draws subjects from either a military Service or another OSD component, then you must obtain DoD internal information collection approval and an RCS (Report Control Symbol) from the DoD Internal Reports Manager. 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.

4.1.2 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.

4.2.0 Privacy Requirements for Data

4.2.1 The Federal Privacy Act (reference (m)) applies to all 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 DoD Directive 6025.18 (reference (p)), applies. 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.

5.0 Compensation of Federal Employees Participating as Subjects in Research

5.1.0 Paying Federal Subjects for research participation

5.1.1 Reference (i) contains the guidance on the use of federal moneys to pay subjects of research but is 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. The regulations regarding paying federal employees are outlined in references (e)-(h). Any federal employee who has questions regarding their ability to accept compensation should be referred to the ethics counselor for their command or organization.

6.0 Consent Issues

6.1 Privacy and Confidentiality Issues for Military Personnel

Some medical and psychological diagnoses can lead to limitation of duties or discharge of military personnel. Depending on the circumstances of the research, a researcher may or may not be able to promise confidentiality of the subject's answers. For more information see paragraph 116 of reference (c).

6.2 Who subjects may contact with concerns

When a P&R institution has primary responsibility for the research or in other studies as appropriate, then potential subjects should be told during the informed consent process that they may report concerns regarding the research to the Human Research Protection Program oversight office.

7.0 Medical or Study Monitor

Per paragraph 4.4.3 of reference (c), all greater than minimal risk studies require a medical monitor and the definition of a medical monitor within DoD differs from the industry definition.

8.0 Consent Process Special Information

8.1 Medical Care for Research Related Injury

8.1.1 32 C.F.R. 219.116 requires, for research involving more than minimal risk, that potential subjects be provided with an explanation as to whether any compensation or medical treatment is available in the case of unanticipated problems or injury. Participation in DoD research does not provide an entitlement to care under the TRICARE program.