A Primer for Conducting Department of Defense (DOD) Funded Human Research With Military Populations

Background: DOD Instruction (DODI) 3216.02 *"Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research"* governs all DOD-supported and -conducted research involving human anatomical substances, human data, and human subjects. The DODI requires review and approval by a Human Research Protection Official prior to implementation of DOD-supported research; the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections, Human Research Protection Office (ORP HRPO) conducts the DODI-required review and approval for USAMRDC-funded research. This administrative review requirement is in addition to local Institutional Review Board (IRB) or Ethics Committee review. Additional ORP HRPO information can be found at: https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo

Research with DOD-affiliated personnel and/or their data: The DODI defines DOD-affiliated personnel as Service Members, Reserve Service Members, National Guard members, DOD civilians, and DOD contractors. If the proposed research involves access to DoD-affiliated personnel, their data, and/or DOD facilities, a letter of support from the DOD Component or commander of military facilities or units in which recruitment will occur is required. This is a critical requirement, and requires pre-planning by investigators. Investigators attempting to access DOD-affiliated personnel as research subjects should consider seeking collaboration with a military investigator who has familiarity with service-specific requirements to obtain access to subjects, for example, accessing Army National Guard/Reserve or Special Operations populations.

Additional DODI requirements for research with DOD-affiliated personnel include:

- If the study includes any risks to DOD-affiliated personnel's fitness for duty (e.g., health, availability to perform job, data breach), the informed consent document must inform them about these risks and that they should seek command guidance before participating.
- If applicable, the consent document must disclose any potential risks for the revocation of clearance, credentials, or other privileged access or duty.
- Appropriate measures must be in place to prohibit military and civilian supervisors, officers, and others in the chain of command from influencing their subordinates to participate in the study.
- Military and civilian supervisors, officers, and others in the chain of command may not be present during the recruitment or consent process.
- For greater than minimal risk research in which DOD-affiliated personnel are recruited in a group setting, an ombudsman must be identified.

Compensation of federal personnel in research studies: DOD-specific prohibitions exist for compensation of Service Members and federal civilian employees for participation in research while on duty. Investigators who plan to compensate subjects may need to ascertain subjects' status in order to comply with the requirements below. Investigators should describe their plan for this assessment of federal employee status in the IRB application. The following provides a summary of permissible compensation and the source(s) of compensation:

On-duty federal personnel including Service Members:

- Up to $50 for blood draws
- Compensation is not allowed for general research participation

Off-duty federal personnel including Service Members:

- Up to $50 for blood draws

- Compensation is allowed for general research participation, as approved by the IRB. Payment may not come directly from a federal source. Payment from a federal contractor or non-federal source is permissible.

Non-federal personnel:

- Up to $50 for blood draws
- Compensation is allowed for general research participation, as approved by theIRB. Payment may come from a federal or non-federal source.

Access to government data sources: Investigators seeking to conduct research requiring access to government data sources must understand access requirements and where necessary, include a qualified government collaborator. Research proposing access to Military Health System data sources (e.g. DOD Trauma Registry, Behavioral Health Data Portal, etc.) will require a collaborator who acts as the Government Sponsor. This individual must be Department of Defense civilian or uniformed Service Member and bears the responsibility for safeguarding data and ensuring all applicable DOD and Federal requirements are met by the non-Government collaborators. A Data Sharing Agreement (DSA) is required before any access to any MHS system is granted. Additional DSA guidance can be found at: https://health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/Submit-a-Data-Sharing-Application

Research involving large scale genomic data (LSGD) collected from DOD-affiliated personnel: DOD-conducted or DOD-supported research involving LSGD collected from DOD-affiliated personnel is subject to requirements for additional Component-level security review. Investigators must also apply for a Certificate of Confidentiality from the National Institutes of Health for all LSGD research.

Use of common data elements and data sharing for psychological health research: The National Research Action Plan recommends the use of common data elements (CDEs) to facilitate sharing of data to promote collaboration, accelerate research, and advance knowledge on characterization, prevention, diagnosis, and treatment of psychological health disorders and post- traumatic stress disorders. The USAMRDC strongly recommends that investigators incorporate CDEs appropriate to each field of study, such as the PhenX Core and Specialty collections (which are available in the Mental Health Research, Substance Abuse and Addiction, and Research Domains Collections of the PhenX Toolkit: ***https://www.phenxtoolkit.org/index.php*** into studies involving human subjects as applicable.

Traumatic brain injury (TBI) research data may be required to be collected in accordance with established TBI CDE guidelines for submission to the Federal Interagency TBI Research (FITBIR), https://fitbir.nih.gov/content/data-dictionary, to include data required to generate a FITBIR Global Unique Identifier (GUID). Specific data fields are required for generation of a GUID and researchers should review the FITBIR informational page on the GUID and GUID generation tool, https://fitbir.nih.gov/content/global-unique-identifier. Use of Unique Data Elements (UDEs) are strongly discouraged unless the research question warrants inclusion. Acceptance of UDEs and non-GUID identifiers (i.e. pseudo-GUIDs) is subject to approval of the program office.

***For studies that will enroll subjects with psychological health disorders*:** Investigators may be requested to submit data to the National Institute of Mental Health Data Archive; https://data-archive.nimh.nih.gov. Appropriate language must be included in the consent form to facilitate this.

If the research involves military families and children: In accordance with DODI 1402.5, *"Criminal History Background Checks on Individuals In Child Care Services"* and Army Directive 2014-23, "*Child*

Care National Agency Check and Inquiries (CNACI)," background investigations are required for all individuals who have regular contact with military dependents under 18 years of age. All individuals who regularly interact with children under 18 years of age in Army sponsored and sanctioned programs must undergo specific initial background checks and periodic re-verifications. Investigators who propose work involving contact with military dependents under 18 years of age should plan for the additional time and funds required for such investigations.

Per Department of Defense Education Activity (DODEA) Administrative Instruction 2071.3 *"Research Study Request"*, DODEA must approve research studies involving DODEA school personnel, school facilities, students, sponsors, and/or data. Investigators proposing to conduct any research activities involving DODEA schools should plan for the additional time (~3-6 months) and effort required to obtain approval from DoDEA to conduct such activities. Procedures and requirements for the review and approval of a research study request can be found at:
http://www.dodea.edu/datacenter/research/requests.cfm

Per Army Regulation, AR 608-18, *"The Family Advocacy Program"*, The Family Advocacy Research Subcommittee will review, coordinate, and recommend approval and dissemination of all family advocacy research, evaluation projects, and research publications within the department of the Army.

Guidance for Research Studies Involving US Army Special Operations Command (USASOC): Per USASOC policy 24-18, "Use and Protection of Human Subjects in Research", studies involving USASOC Soldiers as human subjects require additional review by the USASOC Research Advisory Committee and Human Subjects Research Board.

Where Can I Learn More?

CDMRP: https://cdmrp.army.mil/

DOD Unique Information for Investigators: https://ebrap.org/eBRAP/public/Program.htm

Learn About Military Culture: https://deploymentpsych.org/military-culture

United States Army Medical Research and Development Command:
https://mrmc.amedd.army.mil/index.cfm

ORP HRPO Submission Forms and Guidance:
https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo