A Primer for Conducting Department of Defense (DoD) Funded Human Research With Military Populations - June 2019

If the Research Involves the Use of DoD Personnel and Resources: All DoD-funded research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the United States Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections, Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. The HRPO is mandated to comply with DoD Instruction (DoDI) 3216.02 *"Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research"* which governs all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC.

Additional HRPO guidance can be found at:
https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo

If the proposed research involves access to active duty military populations and/or DoD resources or databases, a letter of support from commander of military facilities or units in which recruitment will occur is required for final approval by the HRPO. This is a critical requirement. Investigators attempting to access military research subjects are advised to seek collaboration with a military investigator who will be familiar with service-specific requirements to obtaining access to subjects. Commanders must be informed about the research to be conducted, and if they agree to support the research, they may choose to facilitate access to subjects. However, commanders cannot encourage or order personnel to participate in research. All participation is voluntary. Note that some military sites may also require that each subject seek written permission from their supervisor prior to participation in research studies.

Investigators seeking to conduct research requiring access to government data sources are strongly encouraged to 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

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 USAMRMC strongly encourages investigators to 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 all 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/informatics system, to include data required to generate FITBIR Global Unique Identifier (GUID). Specific data fields are required for generation of a GUID and researchers are strongly encouraged to 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, or another data repository to be identified by the Government.

If the Research Involves Military Families and Children: In accordance with Department of Defense Instruction (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 are required to 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 approval is required for 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 Targeting DoD Personnel for Survey Research: Protocols that target DoD personnel for research in which the primary data collection tool is a survey require additional administrative review per DoDI 1100.13 *"Surveys of DoD Personnel"*. Investigators will need to coordinate with the US Army Medical Research and Materiel Command, Human Research Protection Office, to identify current submission requirements.

Compensation of DoD Personnel in Research Studies: The DoD has very specific requirements regarding compensation paid to DoD employees, whether they are active duty military or DoD civilian employees. Guidance can be found at DoDI 3216.02, *"Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research"* Encl. 3 para 11. Investigators who plan to compensate subjects may need to ask subjects about their military status in order to comply with the requirements below. Investigators should describe their plan for this assessment of military status in the IRB application. Please visit the following link for additional guidance:

https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo

Summary of current compensation plan for federal personnel including military:
On-duty federal personnel including military members:

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

Off-duty federal personnel including military 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 the IRB. Payment may come from a federal or non-federal source.

Cooperative R&D Agreements: A Cooperative Research and Development Agreement (CRADA) is a written agreement between one or more federal laboratories and one or more non-federal parties under which the government, through its laboratories, provides personnel, facilities, equipment or other resources with or without reimbursement (but not funds to non-federal parties). The non-federal parties provide personnel, funds, services, facilities, equipment or other resources to conduct specific research or development efforts. CRADAs are authorized by 15 U.S.C. 3710a.

CRADAs provide an easy way to collaborate with federal laboratories. CRADAs allow federal researchers to exchange technical expertise with non-federal partners, and to accept reimbursement for research conducted under the CRADA. CRADAs also protect a researcher's rights to inventions. CRADAs are appropriate when ideas, staff, materials, and equipment are to be exchanged over a period of time for the purpose of collaboration and/or an invention may result.

CRADAs must involve at least one non-federal party. In addition to federal laboratories, the other participants in a CRADA may be one or more of the following:

- Private corporations (U.S. or foreign)
- Nonprofit and not-for-profit institutions (U.S. or foreign)
- State and local governments (U.S.)
- Other federal agencies (U.S.)

Where Can I Learn More?

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

Cooperative Research Agreements: https://www.arl.army.mil/www/default.cfm?page=14

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: https://mrmc.amedd.army.mil/index.cfm

Human Research Protection Office Submission Forms and Guidance:
https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo