Guidance for Conducting Human Subjects Research with Department of War Affiliated Personnel or Military Beneficiaries

This document highlights special requirements and considerations related to human subjects research (HSR) involving Department of War (DOW)-affiliated personnel or military beneficiaries to help investigators make plans when applying for Congressionally Directed Medical Research Programs (CDMRP) funding.

Department of Defense Instruction (DODI) 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DOD-Conducted and -Supported Research", governs all DOW-supported and -conducted HSR, including research involving military beneficiaries or **DOW-affiliated personnel**, defined as Service members, Reserve Service members, National Guard members, DOW civilians, and DOW contractors.

- **Command or Component Approvals**:
  - If the HSR involves DOW-affiliated personnel, the lead investigator must receive approval from the DOW-affiliated personnel's command or DOW Component to conduct the research. If the HSR takes place on a DOW facility, the lead investigator must also receive approval from the command or DOW Component responsible for the facility.[1,2]
  - If the HSR includes any risks to the fitness for duty (e.g. health, availability to perform job, data breach) of DOW-affiliated personnel, the informed consent document (ICD) must inform DOW-affiliated personnel about these risks and that they should seek command or Component guidance before participating.
  - Military and civilian supervisors, officers, and others in the chain of command are prohibited from influencing their subordinates to participate in HSR.
  - Military and civilian supervisors, officers, and others in the chain of command must not be present at any HSR participant recruitment sessions or during the HSR consent process for DOW-affiliated personnel.

[1]The CDMRP requires applicants to provide a letter of support signed by the *lowest-ranking person with approval authority* confirming access to active-duty military populations and/or DOW resources or databases. Investigators should consider seeking collaboration with a military investigator who has familiarity with *service-specific* requirements to obtain access to subjects.

[2]Investigators planning to recruit DOW-affiliated personnel online are strongly encouraged to verify candidate's DOW affiliation. Some tools/methods for verification are: the Defense Manpower Data Center Service Members Civil Relief Act website, milConnect, the Department of Defense Civilian Personnel Data System website, requesting copies DD Form 214 (Certificate of Release or Discharge), requesting copies of Leave and Earnings Statement.

- **Institutional Review Board (IRB) or Office of Human Research Oversight (OHRO) Review**:
  - Federal-wide assurance is required when conducting HSR. Institutions without federal assurance may enter into individual investigator agreements to associate with an institution with federal assurance.
  - DODI 3216.02 requires review and approval by a Human Research Protection Official prior to implementation of DOW-supported and -conducted HSR, including

HSR involving DOW-affiliated personnel. This secondary administrative review requirement is in addition to local IRB or Ethics Committee review.[3]

- To approve HSR involving DOW-affiliated personnel, the IRB or OHRO must determine whether the following requirements have been satisfied:
  - The consent documentation must include, if applicable, potential risks for the revocation of clearance, credentials, or other privileged access or duty.
  - For research involving recruitment of DOW-affiliated personnel in HSR determined greater than minimal risk, as defined by Part 219 of Title 32, CFR, and when HSR recruitment occurs in a group setting, the IRB must appoint an ombudsperson.

[3]For CDMRP-funded HSRs, the Defense Health Agency (DHA) Research and Development, U.S. Army Medical Research and Development Command (USAMRDC) OHRO conducts the DODI-required review and approval. Additional OHRO information can be found at: https://mrdc.health.mil/index.cfm/resources/research_protections/ohro

- **Age Consideration**: Service members and all Reserve Component and National Guard members in a federal duty status are considered for purposes of this issuance, to be adults. If a Service member, Reserve Component or National Guard member in federal duty status, student at a Service Academy, or trainee is under 18 years of age, the IRB must carefully consider the HSR recruitment process and the necessity of including such member as a human subject.

- **Compensation**: Compensation to DOW-affiliated personnel for participation in research while on duty is prohibited in accordance with Title 5, U.S.C., with particular reference to Subparts G and H, with some exceptions for purposes consistent with Section 30 of Title 24, U.S.C, “Payments to donors of blood for persons undergoing treatment at Government expense”.[4]

[4]Investigators who plan to compensate subjects may need to ascertain subjects’ duty status to comply with DODI 3216.02 and Title 24, U.S.C., Section 30. Investigators should describe their plan for this assessment of federal employee status in the IRB application.

- **Research involving large-scale genomic data (LSGD) collected on DOW-affiliated personnel**:
  - The disclosure of DOW-affiliated personnel’s genomic data may pose a risk to national security; accordingly, such research requires administrative, technical, and physical safeguards commensurate with risk, including the secondary use or sharing of de-identified data or specimens.
  - All research involving LSGD collected from DOW-affiliated personnel will apply an HHS Certificate of Confidentiality pursuant to Title 42, U.S.C., and Public Law 114-255.
  - Research involving LSGD collected from DOW-affiliated personnel is subject to DOW Component security review to ensure the adequacy of the proposed administrative, technical, and physical safeguards, including the secondary use or sharing of de-identified data or specimens.

Certain types of HSR studies are regulated by additional DODIs or other policy documents. For example:

- **Information collections involving the use of surveys and data collection instruments:** DODI 1100.13, “DOD Surveys”, governs policies, assigns responsibilities, and provides procedures for information collections involving the use of surveys. Surveys are defined as “systematic data collections using personal or telephonic interviews or self-administered questionnaires, in paper or digital format, from a sample or census of 10 or more persons” per DOW Manual 8910.01.
    - The following types of survey will require administrative review per DODI 1100.13:
        - Surveys requiring participation of personnel from more than one DOW or Office of the Secretary of War (OSW) Component.
        - Surveys requiring participation of DOW personnel that are requested by an external organization.
        - Surveys of members of the public (including government contractors) conducted by any DOW or OSW Component.
    - Per DOW Manual 8910.01, facts or opinions “from individuals (including individuals in control groups) under treatment or clinical examination in connection with research” are ***not*** considered public information collections. Refer to DOW Manual 8910.01 for additional exemptions and items not considered public information collections.
    - During Human Research Protection Official review, the OHRO *will only apply DOW survey requirements when the primary purpose of the effort is to conduct a survey. It does not apply to research that may use survey instruments as part of data collection activities in support of research and development.* If the research under review does not solely involve conducting a survey requiring participation of Service Member personnel from more than one DOW or OSW Component, these requirements do not apply.

- **Research 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.

- **Research Involving Military Dependents under 18 years of age**: 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,” 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 DOW 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.

- **Research involving Department of War Education Activity (DoWEA) schools**: Per DoWEA Regulation 2071.2 “Research Approval Process”, research involving DoWEA personnel, facilities, students, sponsors, or non-publicly available data “conducted by noncontractual agencies, individuals or groups of individuals” must be approved by DoWEA. Refer to http://www.dodea.edu/datacenter/research/requests.cfm for information on how to submit a research study request.

- **Family Advocacy Research**: 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.

- ***Accessing Military Health System data sources***: Per the DHA Privacy and Civil Liberties Office, research proposing access to Military Health System data sources (e.g. DOW Trauma Registry, Behavioral Health Data Portal, etc.) will require a collaborator who acts as the Government Sponsor.[5] This individual must be a DOW civilian or uniformed Service Member and bears the responsibility for safeguarding data and ensuring all applicable DOW 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://www.health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/Data-Sharing-Agreements https://health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/Submit-a-Data-Sharing-Application

[5]The CDMRP will **not** serve as the Government sponsor or signatory.