

NOTICE OF FUNDING OPPORTUNITY

for the

Department of Defense (DoD)

Defense Health Agency (DHA)

Military Health System Research Program (MHSRP)

Announcement Type: Initial Announcement

Funding Opportunity Number: HT9425-25-MHSRP

Assistance Listing Number: 12.007 – Military Health System Research

SUBMISSION AND REVIEW DATES AND TIMES

- LOI Submission Deadline: 5:00 p.m. Eastern Time (ET) 10 June 2024
- Invitation to Submit an Application Deadline: 5:00 p.m. ET, 28 June 2024
- Application Submission Deadline: 5:00 p.m. ET, 20 September 2024
 - Scientific and Programmatic Review: February 2025

Table of Contents

A. Program Description...	3
• MHS Description...	3
• MHSR Priority Topic Areas	4
• Clinical Priority Areas	5
B. Eligibility Information...	6
• Eligible Applicants...	6
• Number of Submissions...	6
• Other Information...	6
C. Federal Award Information...	7
D. Application and Submission Information...	8
• Submitting an Application.....	8
• Full Application and Submission Information.....	12
• Submission Dates and Times	16
• Funding Restrictions	16
• Other Submission Requirements	17
E. Application Review Information	19
• Proposal Evaluation Criteria and Selection Information	19
• Scientific Technical Review	19
• Programmatic Review.....	20
• Rejection Criteria.....	21
F. Federal Award Information.....	22
• Federal Award Notices	22
• Administrative and National Policy Requirements	22
• Reporting... ..	24
G. Federal Award Agency Contacts	26
H. Other Information	26
I. Appendix: Statement of Substantial Involvement	29

A. Program Description

The Military Health System Research Program (MHSRP) provides research grants on topic areas directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD (HA)) and the Leadership of the Defense Health Agency (DHA). The intent of MHSR is to foster research capability and capacity that supports the Military Health System (MHS) as a learning health system and to mature as an integrated health system focused on Ready Reliable Care that improves outcomes for patients, staff, and the enterprise.

The MHSRP funds research that examines **factors that affect the enterprise** in terms of economics/cost, quality, outcomes, variation, policies, and how they impact health readiness. The goal is to identify and characterize the factors that influence the efficiency and effectiveness of MHS care delivery. Knowledge obtained from this research should support evidence-based policy and decision-making at the strategic and front-line levels. This Notice of Funding Opportunity (NOFO) seeks rigorous **collaborative** health system research that has the potential to innovate military and civilian health care. The goal is to enhance data-driven evidence that optimizes the MHS delivery of health care and improves the health of beneficiaries. This NOFO is intended to solicit **Intramural and Extramural Military Health System Research** aligned with DHA priority research areas.

MHS Description:

The MHS is one of America's largest and most complex health care systems that provides universal access to 9.6 million beneficiaries eligible for care, which include Service members (Active and Reserve) and their families, retirees, and their families. (<https://www.tricare.mil/Plans/Eligibility>). The MHS currently operates 475 hospitals and clinics, and 248 dental clinics located on military installations around the world. These facilities are subject to the same requirements for accreditation as other United States (US) hospitals with demands to improve quality, safety, costs, and outcomes, including the additional requirement to improve military medical readiness for 1.3 million Active-Duty Service members. The National Defense Authorization Act for Fiscal Year (FY) 2017, Section 702, requires the consolidation of all Services' Military Treatment Facilities (MTFs) under the DHA.

The MHS is managed by the TRICARE health care program, which provides comprehensive coverage to all DoD beneficiaries. The TRICARE health care program brings together 51 inpatient hospitals and medical centers (37 in the US), 424 ambulatory care and occupational health clinics (373 in the US), 248 dental clinics (204 in US), and 251 veterinary facilities (206 in US). TRICARE works with its network and non-network TRICARE-authorized civilian health care professionals, institutions, pharmacies, and suppliers (often referred to as "purchased care") to provide access to the full array of high-quality health care services while maintaining the capability to support military operations.

Data on the 9.6 million beneficiaries and the TRICARE health plan is captured in the Military Data Repository.

TRICARE has several different plans, including TRICARE Prime, TRICARE Select, and TRICARE for Life (TFL). TRICARE Prime benefits are comparable to the health maintenance organization

offered in many areas. TRICARE Prime's point-of-service option permits enrollees to obtain care from TRICARE authorized providers other than the assigned Primary Care Manager (PCM) without a referral, but with deductibles and cost shares significantly higher than those under TRICARE Prime. TRICARE Select is a fee-for-service plan available within the US through any TRICARE authorized provider, where patient costs vary based upon sponsor's military status. TFL is the Medicare wraparound coverage for TRICARE-eligible beneficiaries who have both Medicare Parts A and B as their primary health care coverage. In most instances, Medicare pays first, then TRICARE pays second for TRICARE covered services. Most TRICARE health plans meet the requirements for minimum essential coverage under the Affordable Care Act.

To access the current Annual Evaluation of the TRICARE Program see: <https://www.health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Health-Care-Program-Evaluation/Annual-Evaluation-of-the-TRICARE-Program>.

MHSR Priority Topic Areas:

Research must examine the organization, delivery, and financial cost of healthcare, producing evidence that impacts policy and decision-making within the MHS. The research must enhance the efficiency and effectiveness of the MHS to be considered for funding. The research aims should address at least one of the Priority Topic Area(s).

- a. Economics and Cost:** Research on the factors that shape the MHS cost, drive demand and utilization, and influence cost in either TRICARE direct or purchased care systems; issues related to efficiency, effectiveness, value and behavior in the production, and utilization health care in terms of costs, charges, and expenditures; the impact of technologies on care delivery and cost; and the impact of workforce, recruitment, and retention of medical personnel. Research that delineates value-based care within the MHS in both purchased and direct care; pre- and post- studies to evaluate the impact of the structure of the TRICARE contract on patient care.
- b. Quality:** Research which examines the degree to which health services for individuals and populations are safe, effective, patient-centered, timely, efficient, and equitable with the outcome of increasing the likelihood of improved health. Research should measure the impact of standardizing clinical practice through clinical practice guidelines, evidence-based practices, and process interventions on the health of the population/sub-population.
- c. Outcomes:** Health outcome research identifies and measures the factors which impact a population of patients and examines the system level factors which influence achievement of the Quadruple Aim "better health." Comparison to private sector efforts or between direct and purchased care should be considered. Health outcomes research incorporates more than clinical outcomes, it must include consideration of the financial impact, health, quality of life, and measurement of indicators that predict factors

important to patients and patient experience at the enterprise, geographic market level, or sub-population levels.

- d. **Variation:** Studies that examine the factors that influence unwarranted differences in quality, utilization, cost, or outcomes within the MHS and the implications to the enterprise as a system of care.
- e. **Health Readiness:** Burden of disease associated with the health and risk factors associated with the MHS populations that effect Active-Duty Service Members ability to deploy. Implications of disease burden as an indicator of medical readiness, potential impact to staffing, network utilization, and cost for direct care and/or purchased care.
- f. **Health System:** Research related to the impact of the significant changes in policy, structure, or funding of healthcare system; impact of policy and system change to healthcare cost, quality, utilization, health outcomes, manpower/staffing, or health care readiness; comparisons between direct and private care, or care within the private sector should be considered; measurement of the impact of policy changes to the TRICARE benefit structure on utilization and cost to the system.

Clinical Priority Areas:

The proposals must emphasize one of the listed **Clinical Priority Areas:**

- a. Cardiovascular Health
- b. Women's Health
- c. Primary Care
- d. Specialty Care
- e. Sensory Health
- f. Dental Care
- g. Surgical Care
- h. Telehealth
- i. Nutritional Care

Proposals must address **one or more of the MHSR priority topic areas and one of the clinical priority** areas listed. All research should consider including in their analysis an examination the system variables listed below:

- a. Disparities in care in terms of age, race, gender, rank, service
- b. Manpower and staffing models should include:
 - a. Physicians, nurses, allied health professionals and administrative support
- c. Impact of major transformational change resulting from Genesis
- d. Difference between care delivered in the direct vs. private care system

B. Eligibility Information

Eligible Applicants:

LOIs and Full Proposals for this funding opportunity may be submitted by investigators, uniformed or civilian staff who work for DoD or non-DoD organizations, as defined below. DHA encourages applications from Minority Serving Institutions (MSI) that include Historically Black Colleges and Universities and others as defined at: <https://www.doi.gov/pmb/eeo/doi-minority-serving-institutions-program>.

- a. **Extramural Organization:** An eligible non-DoD organization. Examples of extramural organizations include academic institutions, nonprofit organizations, and other federal government organizations (other than DoD).
 - Federally Funded Research and Development Centers (FFRDCs) are not eligible to directly receive awards under this NOFO. However, teaming arrangements between FFRDCs and eligible organizations are allowed if permitted under the sponsoring agreement between the federal government and the specific FFRDC.
 - Government agencies within the US: Local, state, and non-DoD federal government agencies are eligible to the extent that proposals do not overlap with their fully funded internal programs. Such agencies are required to explain how their proposals do not overlap with their internal programs.
- b. **Intramural DoD Organization:** A facility or group of facilities owned, leased, or otherwise used by Office of the Secretary of Defense, the Military Departments, the Defense Agencies, and all other organizational entities within the DoD; to include DoD laboratories, DoD MTFs, and/or DoD activities embedded within a civilian medical center. Proposals may not overlap with their fully funded internal programs.

Number of Submissions:

An eligible applicant **may submit up to two LOIs for consideration**, but **only one (1) LOI** may be selected. Multiple awards to an extramural and/or intramural organization is possible under this announcement.

- a. For applicants with dual appointments with a Federal Agency and a university, please **clearly** identify the "single" organization or affiliation which will have legal authority over funds resulting from the award.
- b. It is **recommended** that extramural organizations partner with DoD partners to improve understanding of the context of the research.
- c. Full proposals from a DoD intramural applicant **must include a succession plan** that discusses the transfer of the research in the event the applicant deploys or has a change of duty station. Additionally, a letter of support from their commanding officer is required. In the event of such a change please notify the Grants Officer as soon as possible.

Other Information:

- a. There is no cost sharing or match requirement.
- b. **All partnerships or contract agreements, including funds management, are the responsibility of the applicant's organization and should be in place prior to receiving the award of funds.**
- c. Grants or cooperative agreements will be awarded to organizations, not to individuals.
- d. This funding opportunity is a multi-step process.
 - LOIs will be subject to a general review to determine if the research intent aligns with DHA's priority research area and objectives.
 - If selected, the applicant will be invited to submit a full proposal for a technical merit review, which includes both scientific and programmatic reviews.
 - Resubmission of the LOI or failure to submit a full proposal by the proposal deadline will result in immediate dismissal from further review.
- e. The Federal Assistance Certifications Report (completed as part of the SAM registration) is a required attestation that the entity will abide by the requirements of the U.S. laws and regulations; therefore, as applicable, you are still required to submit any documentation, including the SF LLL Disclosure of Lobbying Activities (if applicable), and informing DoD of unpaid delinquent tax liability or a felony conviction under any Federal law. If applicable, the SF LLL should be submitted with the SF 424 form. See Section F. Federal Award Information for additional information.
 - DoD required certifications: By checking "I agree" in block 17 of the SF 424 (see below) and signing the application as the authorizing official, you are certifying that your institution will be in compliance with these additional requirements:
 - i. Institutions of higher education must certify compliance with 10 U.S.C 983, *Institutions Of Higher Education That Prevent ROTC Access Or Military Recruiting On Campus: Denial Of Grants And Contracts From Department Of Defense, Department Of Education, And Certain Other Departments And Agencies*, and 32 C.F.R. 216 *Military Recruiting And Reserve Officer Training Corps Program Access To Institutions Of Higher Education*.
 - ii. Recipient will not require any of its employees, contractors, or sub-recipients seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting those employees, contractors, sub-recipients from lawfully reporting that waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

C. Federal Award Information

The following information applies to awards issued under this announcement:

- The anticipated number of awards for this program in FY24 will vary, available funds

are anticipated to be \$10,000,000, with the number of awards being determined based on the availability of funds. Both intramural and extramural agreements will be made. All funding decisions are final.

- Full proposals will only be accepted from eligible applicants who submitted an LOI **and** received an invitation to submit a full proposal.
- The DHA reserves the right to fund all, some, or none of the proposals submitted, and may elect to fund only part of any or all proposals. Funding may occur incrementally or completely.

This funding opportunity will result in grants or cooperative agreements, using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). General guidance and procedures for proposal submission are described at www.grants.gov. If the government will have substantial involvement in the project as outlined in Appendix K of this notice, a cooperative agreement will be awarded.

D. Application and Submission Information

Submitting an Application:

DoD will only accept proposals submitted through Grants.gov on or before the date specified. Read the instructions below about registering to apply for DoD funds. Applicants should read the registration instructions carefully and prepare the information requested before beginning the registration process. Reviewing and assembling the required information before beginning the registration process will alleviate last-minute searches for required information.

Organizations must have a Unique Entity Identifier (UEI) Number, active System for Award Management (SAM) registration, and Grants.gov account to apply for grants. If individual applicants are eligible to apply for this funding opportunity, then you may begin with step 3, Create a Grants.gov Account, listed below.

Creating a Grants.gov account can be completed online in minutes, but UEI and SAM registrations may take several weeks. Therefore, an organization's registration should be done in sufficient time to ensure it does not impact the entity's ability to meet required application submission deadlines. Note: Failure to allow enough time for the systems to complete the registration is not considered a valid explanation for why grants.gov did not accept the proposals.

Complete organization instructions can be found on Grants.gov at:

<https://www.grants.gov/web/grants/applicants/organization-registration.html>

- 1) *Register with SAM*: The applicant organization must be registered as an entity in SAM (<https://www.sam.gov/content/home>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. As published in the Federal Register, July 10, 2019, (<https://www.federalregister.gov/documents/2019/07/10/2019-14665/unique-entity-id-standard-for-awards-management>), the UEI for awards management generated through SAM will be used instead of the Data Universal Numbering System (DUNS) number as of April 2022. All federal awards including, but not limited to, contracts, grants, and

cooperative agreements will use the UEI. USAMRDC will transition to use of the UEI beginning with FY22 announcements and utilize the latest SF424, which includes the UEI. The DUNS will no longer be accepted. Applicant organizations will not go to a third-party website to obtain an identifier. During the transition, your SAM registration will automatically be assigned a new UEI displayed in SAM. (For more information, visit the General Services Administration: <https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-information-kit/unique-entity-identifier-update>.) Current SAM.gov registrants are assigned their UEI and can view it within SAM.gov.

2) *Create a Grants.gov Account*: The next step is to register an account with Grants.gov. Follow the on-screen instructions or refer to the detailed instructions at <https://www.grants.gov/applicants/applicant-registration>

3) *Add a Profile to a Grants.gov Account*: A profile in Grants.gov corresponds to a single applicant organization the user represents (i.e., an applicant) or an individual applicant. If you work for or consult with multiple organizations and have a profile for each, you may log in to one Grants.gov account to access all your grant applications. To add an organizational profile to your Grants.gov account, enter the UEI Number for the organization in the UEI field while adding a profile. For more detailed instructions about creating a profile on Grants.gov, refer to: <https://www.grants.gov/applicants/applicant-registration/add-profile>

4) *EBiz POC Authorized Profile Roles*: After you register with Grants.gov and create an Organization Applicant Profile, the organization applicant's request for Grants.gov roles and access is sent to the EBiz POC. The EBiz POC will then log in to Grants.gov and authorize the appropriate roles, which may include the Authorized Organization Representative (AOR) role, thereby giving you permission to complete and submit applications on behalf of the organization. You will be able to submit your application online any time after you have been assigned the AOR role. For more detailed instructions about creating a profile on Grants.gov, refer to: <https://www.grants.gov/applicants/applicant-registration/ebiz-poc-authorizes-profile-roles>

5) *Track Role Status*: To track your role request, refer to: <https://www.grants.gov/applicants/applicant-registration/track-profile-role-status>

Electronic Signature: When applications are submitted through Grants.gov, the name of the organization applicant with the AOR role that submitted the application is inserted into the signature line of the application, serving as the electronic signature. The EBiz POC **must** authorize people who are able to make legally binding commitments on behalf of the organization as a user with the AOR role; **this step is often missed, and it is crucial for valid and timely submissions.**

Letter of Intent (LOI):

- A LOI is the first step in the proposal process. A LOI provides an opportunity to assess if there is a match between the intended research and the program priorities. Please write a concise and persuasive document regarding how the research will identify, solve, or add to the knowledge base.
- The MHSR program committee will review all LOIs submitted. Applicants whose LOI aligns with the stated program priority areas as demonstrated by clearly stated objectives, aims, and appropriate methods will then be **invited** to submit full proposals for consideration of an award. **LOI are to be submitted to:**
dha.ncr.j-9.mbx.hsr@health.mil.
- **LOI Content Requirement:**

(Format – Calibri 11 point, one-inch margins LOI and all supporting documentation to be submitted as a single PDF labelled {PI Last Name} _FY25_MHSR_ (Institution)

1) General Information Required (1 Page)

- Project title** to be used throughout the grant process
- Contact information:
 - Principal Investigator (PI), including organization
 - DoD affiliation, if any,
 - A succession plan for military personnel associated with the research. A succession plan states what will occur in the event the PI deploys or has a permanent change of duty station.
- If the proposal is from an MSI, clearly state the investigator's institutional status within the MSI.
- Performing organization (i.e., site at which the PI will perform the proposed work) and the submitting organization (i.e., organization submitting the LOI(s) on behalf of the PI).
 - Provide a brief description of the primary institution and facility where the research is expected to be performed.
 - Provide the organization's resource manager/comptroller or equivalent Business Official and Authorized Organizational Representative (AOR) responsible for program administration. (If awarded, this person will be identified in Block 5 of the SF-424 form.)

2) Collaborators and Key Personnel (1 page) – Research Team Description

- Briefly explain how the team's expertise is appropriate and complementary for achieving the research goals. Include information on name, organization, and role of all collaborators and key personnel associated with the LOI proposal (including co-investigators, mentors, collaborators, consultants, and sub-awardees, if applicable).
- Briefly describe the role of the PI, co-PIs (if applicable), key personnel, sub-awards (if applicable), and consultants (if applicable) on the research team,

the expertise each brings to the proposed research, demonstrating that their background and expertise is appropriate.

3) Project Narrative (five-page limit)

The LOI page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, and drawings) used to **briefly** describe the project. **Inclusion of URLs** in the narrative that provide additional information confer an unfair competitive advantage and, thus, **are prohibited** and **will result in rejection of the LOI**. The LOI Narrative should include the following:

- i. **MHSR Priority Topic Area(s):** Identify the FY 2024 DHA MHSR Priority Topic Area(s) that the proposed research addresses.
- ii. **Alignment with Clinical Priority Areas:** Explain how the proposed research is relevant to the identified MHSR and clinical priority areas and supports the MHS.
- iii. **Opening paragraph:** A standalone statement that clearly states the objective of the research.
- iv. **Research Plan:** Briefly explain the issue being addressed, why it was chosen, and who it will impact. Include:
 1. **Background/Rationale:** Briefly present the ideas and reasoning behind the proposed research. Include relevant military **and** civilian literature citations, preliminary and/or pilot data, and/or other evidence that led to the development of the proposed research. Any preliminary data should be from the PI and member(s) of the collaborating team.
 2. **Hypothesis, Specific Aims, and Objectives:** Clearly state the proposed research hypothesis and/or objectives and the specific aims/tasks. **Aims** are statements of intent (i.e., what the research hopes to achieve). **Objectives** are statements that define measurable outcomes (i.e., the steps that will be taken to achieve the desired outcome).
 3. **Theoretical Rationale, Scientific Methods, and Design:** Briefly describe the research approach with information on proposed methods and analysis/evaluation strategies. Describe anticipated outcomes of how this study will enhance knowledge in designated priority areas, as well as expected outcomes. Include a description of study population for studies involving human subjects, include a description of the size and characteristics of the subject population. Include all data sources that require data sharing agreements.
- v. **Military Relevance and Impact:** Describe, if successful, how the proposed study will promote and advance the Military Health System's (MHS) maturation as an integrated health system focused on Ready Reliable Care. Describe how the proposed study will directly or indirectly benefit military Service members and other beneficiaries, as well as how the knowledge can be utilized across the MHS.
- vi. **Timeline and Estimated Total Budget:** Provide the estimated total budget and a timeline to achieve the research plan.

4) Supporting Documentation

- i. **References Cited (one-page limit):** List the references cited (including URLs if available) in the LOI narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- ii. **List Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used.
- iii. **Personnel Biographical Sketches (five-page limit per individual) for PI and Co-PI only:** The NIH Biographical Sketch (non-fellowship) may be used. Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished. Bold or highlight publications relevant to the proposed project. (<https://grants.nih.gov/grants/forms/biosketch.htm>).

Full Application and Submission Information:

All full proposals must be submitted through the website: <https://www.grants.gov>. Proposals will not be accepted by mail or in person. Uninvited proposals will not be reviewed or considered for an award.

For this funding opportunity, each proposal submission must include the complete proposal package requirements established at <https://www.grants.gov>. The completed proposal package shall be submitted by the AOR. **(Format – Calibri 11 point, one-inch margins LOI and all supporting documentation)**

- 1) The proposal package includes the following **mandatory** components:
 - i. **SF-424 Research and Related (R&R) Application for Federal Assistance Form**

- a. **Block 17 – Complete Certification.** Select the “I agree” box to provide the required certifications and assurances. By checking “I Agree” on the SF424 (R&R) block 17 you agree to abide by the following statement: *“By signing this application, I certify (1) to the statements contained in the list of certifications and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001).”*

By checking “I Agree” of the SF424 (R&R) block 17 you abide by the following statement: *‘By signing this application, I certify the proposing entity is in compliance with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 which requires that: (a) the PI and other key personnel*

certify that the current and pending support provided on the proposal is current, accurate, and complete; (B) agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the terms of the award; (c) the PI and other key personnel have been made award of the requirements under Section 223(a)(1) of this Act.”

- ii. **R&R Other Project Information Form**
 - a. Project Abstract – A description of the research, research intent and potential impact written in plain, non-technical language, that can be used with non-researchers. Upload file as “Abstract-technical.pdf”
 - b. Lay Abstract- Written in plain, non-technical language, that can be used with non-researchers. Suitable for use with non-research audience. Upload file as “Abstract-Lay.pdf”
 - c. Project Narrative – Detailed methodology description – **12-page** limit. Upload file as “ProjectNarrative.pdf”. Project Narrative should include:
 - a. Background
 - b. Purpose/Objective
 - c. Aims
 - d. Methodological Approach
 - e. Potential Impact of Research
 - f. Implementation Plan for Research Outcomes
- iii. **Bibliography & Reference Cites**
 - a. Upload file as “BibRef.pdf”
- iv. **Project/Performance Site Location**
 - a. Upload file as “FacilitySupport.pdf”
- v. **R&R Personal Data Form**
 - a. **R&R Senior/Key Personnel Profile (Expanded) Form - PI(s) and Key Personnel Biographical Sketches (five-page limit per individual):**
 - a. Upload file as “Biosketch_LastName.pdf.”
 - b. The NIH Biographical Sketch (non-fellowship) should be used. Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
 - c. Bold or highlight publications relevant to the proposed project. (<https://grants.nih.gov/grants/forms/biosketch.htm>)
 - d. Consistent with National Security Presidential Memoranda-33, individuals are required to disclose grants and contracts associated with participation in programs sponsored by foreign governments, instrumentalities, or entities, including foreign government-sponsored talent recruitment programs. Further, if individuals receive direct or indirect support that is funded by a foreign government-sponsored talent recruitment program, even

where the support is provided through an intermediary and does not require membership in the foreign government-sponsored talent recruitment program, that support must be disclosed. Individuals must also report other foreign government sponsored or affiliated activity. ***“Foreign government-sponsored talent recruitment program” is defined as an effort organized, managed, or funded by a foreign government, or a foreign government instrumentality or entity, to recruit science and technology professionals or students (regardless of citizenship or national origin, or whether having a full-time or part-time position).***

- e. **Positions and Appointments:** List all positions and scientific appointments, both domestic and foreign (including affiliations with foreign entities or governments), held by the PI and all senior/key personnel. This includes titled academic, professional, or institutional appointments, independent of whether remuneration is received and/or whether the position/appointment is full time, part time, or voluntary (including adjunct, visiting, or honorary). Selection to a foreign “talents” or similar-type program must be reported.

• **Resources:** Report all other support including resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of monetary value. This includes but is not limited to foreign financial support, research or laboratory personnel, lab space, scientific materials such as high-value materials that are not freely available (biologics, chemical, model systems, technology, etc.), or other foreign or domestic research support.

• **Other Projects and Activities:** Report all current projects and activities that involve the PI and all senior/key personnel, even if the support received is only in-kind (e.g., office/laboratory space, equipment, supplies, employees). This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, gifts provided with terms or conditions, financial support for laboratory personnel, and participation of student and visiting researchers supported by other sources of funding. Information must be provided for all current support for ongoing projects, whether such support is provided through the applicant organization, through another domestic or foreign organization, or is directly provided to an individual who supports the senior/key personnel’s research efforts.

b. R&R Senior/Key Personnel Current & Pending Support

- a. Upload file as “Support_LastName.pdf” to the appropriate field
 - c. **Conflict of Interest Statements**
 - a. Upload file as “COI_LastName.pdf”
- vi. **R&R Attachments**
 - a. **R&R Multi-Year Budget Form** – for years one and two, applications should reflect the actual needs of the proposed project.
 - a. R&R Sub-Award Budget Attachment Form
 - b. See General Application Instructions for more information about each form. All forms can be found on <https://www.grants.gov>.
 - c. **Statement of Work for subawards**
 - i. Upload as Attachment with file name “SOW.pdf.”
 - b. **Data and Research Resource-Sharing Plan:**
 - a. Upload as Attachment 4 with file name “Sharing.pdf.”
 - c. **Data Management**
 - a. Upload as Attachment 6 with file name “DataManage.pdf”.
 - d. **Letter of Organizational Financial Support for Military Partners:**
 - a. Resource from Manager/Comptroller or appropriate financial officer (If Applicable)
 - b. Upload as Attachment 7 with file name “MilFinancialSupport.pdf”.
 - e. **Letter of Organizational Command Support for Military Partners:**
 - a. MTF, Installation Commander or equivalent Commanders/Directors (If Applicable)
 - b. Upload as Attachment 8 with file name “MilCommandSupport.pdf”.

vii. **Other Notices:**

Each applicant (unless the applicant is an individual or federal awarding agency that is excepted from those requirements under 2 codes of federal regulation (CFR) §25.110(b) or (c), or has an exception approved by the federal awarding agency under 2 CFR §25.110(d)) is required to:

- a. Be registered in the System for Award Management (SAM) before submitting an application.
- b. Provide a valid unique entity identifier (UEI) in its application; and
- c. Continue to always maintain an active SAM registration with current information during which it has an active federal award or an application or plan under consideration by a federal awarding agency.

An award will not be made to an applicant until the applicant has complied with all applicable UEI and SAM requirements and, if an applicant has not fully complied with the requirements by the time DHA is ready to make award, the DHA Grants Officer may determine that the applicant is not

qualified to receive a federal award and use that determination as a basis to make an award to another applicant.

Submission Dates and Times:

- **LOI Submissions:** All LOIs must be submitted by the applicant through the DHA MHSR program mailbox (dha.ncr.j-9.mbx.hsr@health.mil) by date listed on Cover Page. PIs and organizations identified in the LOI **must** be the same as those intended for the subsequent proposal submission. Any changes after submission of the LOI requires contacting the DHA J-9 Technical Representative through the DHA MHSR program mailbox (dha.ncr.j-9.mbx.hsr@health.mil). A change in PI or organization after submission of the LOI will be allowed only at the discretion of the Technical Representative. When emailing the MHSR Program mailbox, please request a read receipt.
- **Proposal Submissions**
 1. All full proposal submissions must be submitted to <https://www.grants.gov> by **date listed on the cover page**. The system will generate a receipt of proposal email.
 2. **There will be no grace periods.** Applicants must be familiar with requirements from <https://www.grants.gov>, including the need for an active SAM registration and an UEI as a Data Universal Numbering System (DUNS) has been phased out.
 3. **LOIs/Proposals Rejections.** Failure to meet the requirements of this PA will result in an immediate rejection. Additional reasons for rejection include:
 - a) Inclusion of URLs, except for links in References Cited and Publication and/or Patent Abstract section.
 - b) Page size is 8.5 inches x 11.0 inches. (Approximately 21.59 cm x 27.94 cm.) and or formatting is not followed – **Calibri 11 point, one-inch margins all the way around**. Sections exceeding the specified page limits will have any pages after the limit removed before review.
 - c) PI does not meet the eligibility criteria.

Funding Restrictions:

- The maximum period of performance is two years.
- The anticipated total costs (direct and indirect) should be budgeted for the entire period of performance. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No award will be made exceeding the stated total costs or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any sub-award (sub-grant or sub-contract) must be included in the total costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum two years.

- Regardless of the period of performance or number of collaborators proposed, the applicant may not exceed the maximum allowable total costs.
- Unallowable Costs:
 - a. Laboratory Costs (reagents, animals, etc)
 - b. Database Development Costs

Other Submission Requirements:

- **Funding to intramural organizations for selected proposals will be dependent on relationships between the Defense Health Agency and the DoD laboratory. Specific agreements between the funding and receiving organization may be required for funding to be transferred.** Final transfer of funds is contingent upon appropriate safety and administrative approvals as well as approved agreements and funding mechanisms. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers.
 - 1) Intramural applicants must provide a detailed Federal Agency Financial Plan after the budget justification information in the Detailed Budget and Justification Form. Proposals must provide a plan delineating how all RDT&E funds will be obligated. The plan must include the funding mechanism(s) and contractual arrangements that will be used to carry over funds between fiscal years, if applicable. ****Note: MHSR awardees will receive FY25 funding which will expire for obligation September 30th, 2026.** The intramural organization must plan accordingly to execute all received funds before they expire.
 - 2) Applicants must provide Letters of Organizational Support from the following:
 - a) Resource Manager/Comptroller: Provide a letter of support from the applicant institution's Resource Manager/Comptroller Office (or appropriate financial point of contact) assuring that the institution will be able to accept these funds, if awarded. If funds are to be sent to multiple sites, include a letter from each site. Proposal letters of support must include mechanism of funding transfer to each institution.
 - b) Commander(s): Provide a letter (or letters) of support from appropriate MTF, Installation Commander, or equivalent Commanders/Directors to ensure access to the facility, research population, and other necessary resources. The Commander should be aware of all submissions and should confirm that the proposed work is both feasible from a technical perspective and relevant from a programmatic and Command perspective.
 - 3) For the MHSR program, funding is only awarded to the prime institution. If the prime is an extramural organization (academia/non-profit), and the intramural lab/organization plans to be a sub-awardee, the prime awardee must be able to fully manage and execute the funding and distribute funds to the sub awardees. The prime

and sub awardees must ensure that appropriate approvals are obtained from their respective organization's resource management and legal teams.

- a) Direct transfer of funds from the recipient to a federal agency is not allowed except under very limited circumstances.

- **Foreign Collaboration Justification:**

- 1) Applications that propose consultant, subaward, consortium, or contractual arrangements with foreign organizations or collaborators employed by foreign organizations/governments are required to demonstrate how one or more of the following conditions have been met:
 - a. The foreign organization or individual(s) employed by foreign organizations/governments contributes unique expertise, organizational capability, facilities, data resources, and/or access to a geographic location or population not generally available to investigators based in the U.S. (or which would require significant effort or time to duplicate) or would potentially significantly advance the health sciences in the United States.

The foreign organization, individual(s) employed by foreign organizations/governments, or project offers significant unique health research opportunities to advance U.S. Military medicine and benefit Service Members, Veterans, their Families.

- **Timely Receipt Requirements and Proof of Timely Submission:**

- 1) The AOR who submitted the application will receive an acknowledgement of receipt and a tracking number (GRANTXXXXXXXX) from Grants.gov with the successful transmission of their application. This AOR will also receive the official date/time stamp and Grants.gov tracking number in an email serving as proof of their timely submission.
- 2) When DoD successfully retrieves the application from Grants.gov, and acknowledges the download of submissions, Grants.gov will provide an electronic acknowledgment of receipt of the application to the email address of the AOR who submitted the application. Again, proof of timely submission shall be the official date and time that Grants.gov receives your application.
- 3) Applicants using slow internet, such as dial-up connections, should be aware that transmission can take some time before Grants.gov receives your application. Again, Grants.gov will provide either an error or a successfully received transmission in the form of an email sent the AOR attempting to submit the application. The Grants.gov Support Center reports that some applicants end the transmission because they think that nothing is occurring during the transmission process. Please be patient and give the system time to process the application.
- 4) **Application Withdrawal:** An applicant may withdraw an application at any time before award by written notice or by email. Notice of withdrawal shall be sent to the Grants Officer identified in this announcement. Withdrawals are effective upon receipt of notice by the Grants Officer.

E. Application Review Information

Proposal Evaluation Criteria and Selection Information:

All full proposals will be evaluated using a two-tier review process. The first tier is a peer review of proposals against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA R&E MHSRP and the OASD(HA), based on (a) scientific and technical merit and (b) the relevance to the mission of the HA/DHA and the MHS Quadruple Aim. The highest-ranked proposals from the first tier of review may not automatically be recommended for funding depending on the second tier, programmatic review.

All review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain evaluation information or to influence the evaluation process. Violations of these prohibitions will result in rejection of the organization's proposal. Violations by applicants that compromise the confidentiality of the review process or are otherwise improper may also result in suspension or debarment from federal awards.

Scientific Technical Review:

- d. General:
 - 1) To determine scientific and technical merit, the evaluators will assess and grade/evaluate Full Proposals according to the criteria below, but the government reserves the right to reconsider based on programmatic needs.
 - 2) To be considered for funding, proposals must address one or more of the MHSR priority topic areas AND one of the clinical priority areas, listed above in the Program Description.
 - 3) Proposals will be scored and ranked based on how well each proposal addresses the priority areas and the requested elements along with the strength of the science listed in the Application and Submission section above.
 - 4) Highly ranked, well-justified projects that address all the requested proposal elements will receive higher ranking scores.

- e. Review Criteria. To determine technical merit, all applications will be evaluated according to the following **scored criteria**, which are listed in decreasing order of importance:
 - 1) Research Objectives
 - a. Research aims

- i. How well the hypothesis or objectives, specific aims, research strategy, methods, and analyses are developed and support successful completion of the project aims.
 - ii. To what extent the proposed research project is feasible and relevant to the MHS as described.
 - iii. How well the application acknowledges potential problems and addresses alternative approaches.
 - iv. How well the study is designed to achieve the research objectives.
- 2) Theoretical Rationale
 - a. How well the study details the variables to be considered, how they are conceptionally defined and related, and how they will be tested.
- 3) Narrative: Scientific Design and Methods
 - a. Impact/Outcomes
 - i. To what degree the successful outcomes of the proposed research will make towards advancing Health System Research
 - ii. To what degree successful research outcomes emanating from the proposed research will clearly demonstrate next step actions for the MHS
 - iii. To what degree successful research outcomes will impact at least one of the MHSR and clinical focus areas.
 - b. Background/Rationale
 - i. How well the study reflects the needs and issues of the MHS and previous studies.
 - c. Personnel/PI Biographical(s)
 - i. To what extent the background and experience of the PI, Partnering PI (if applicable), and other key personnel are appropriate to accomplish the proposed research project.
 - ii. To what degree the levels of effort by the PI, Partnering PI (if applicable), and other key personnel are appropriate to ensure successful conduct of the proposed work.
 - d. Dissemination/Succession Plan
 - i. To what degree is there a demonstration of thoughtful implementation beyond the execution of published papers.
 - ii. To what degree has there been a demonstration of the next steps needed to respond to the research outcomes.
 - e. Proposal Clarity
 - f. Facilities and Resources
 - g. Budget

Programmatic Review:

- a. To make funding recommendations, programmatic reviewers will use the following criteria:
 - 1) Ratings and evaluations of the peer reviewers (e.g., the scored scientific review)
 - 2) Relevance to the mission needs of the MHS/DHA/Services

- 3) Relative innovation and impact to the MHS
- 4) Implementation strategy for research outcomes
- b. The above considerations are not listed in any order of importance. Other factors taken into consideration may include the critical nature of the project, alignment to DoD's initiative, and availability of funding.

Rejection Criteria:

- a. LOI Narrative is missing.
- b. LOI Narrative exceeds page limit.
- c. LOI was submitted by an ineligible organization
- d. Submission of a proposal for which a letter of invitation was not received.
- e. Project Narrative is missing.
- f. Budget is missing.
- g. Personnel from proposing or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- h. The proposal fails to conform to this Funding Opportunity description to the extent that appropriate review cannot be conducted.
- i. Total costs as shown on the DoD Military Budget Form exceed the maximum allowed by this Funding Opportunity. (applies to intramural organizations)
- j. Letters of support are missing.
- k. Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- l. Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- m. The PI does not meet the eligibility criteria.
- n. Sections exceeding the specified page limits will have any pages after the limit removed before review.
 - a. LOI Narrative is missing.
 - b. LOI Narrative exceeds page limit.
 - c. LOI was submitted by an ineligible organization
 - d. Submission of a proposal for which a letter of invitation was not received.
 - e. Project Narrative is missing.
 - f. Budget is missing.
 - g. Personnel from proposing or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
 - h. The proposal fails to conform to this Funding Opportunity description to the extent that appropriate review cannot be conducted.
 - i. Total costs as shown on the DoD Military Budget Form exceed the maximum allowed by this Funding Opportunity. (applies to intramural organizations)
 - j. Letters of support are missing.
 - k. Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
 - l. Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
 - m. The PI does not meet the eligibility criteria.

- n. Sections exceeding the specified page limits will have any pages after the limit removed before review.

F. Federal Award Information

Federal Award Notices: Notification of selection of all applications will be e-mailed by the USAMRAA Grants Officer.

The notification e-mail regarding a successful application must not be regarded as authorization to commit or expend DoD funds. An award signed by the USAMRAA Grants Officer is the authorizing document. Applicants whose applications are recommended for negotiation of award will be contacted by a USAMRAA Grant Specialist to discuss any additional information required for award. This may include representations and certifications, revised budgets or budget explanations, or other information as applicable to the proposed award. The award start date will be determined at this time.

Administrative and National Policy Requirements:

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

Each agreement awarded under this announcement will be governed by the general terms and conditions in effect at the time of the award. Refer to full text of the latest [DoD R&D Terms and Conditions](#) and the [USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions](#) for further information.

A. Certification

Certification of compliance with the national policy requirement regarding lobbying activities is required from all recipients of awards over \$100,000. Submission of this certification is required by 31 USC 1352 and is a prerequisite for making or entering into an award over \$100,000.

Complete SFLLL (Disclosure of Lobbying Activities), if applicable, and attach to Block 18 of the SF424 (Application for Federal Assistance) Form.

Certification for Contracts, Grants, Loans, and Cooperative Agreements

By signing an application, the applicant certifies, to the best of his or her knowledge and belief, that:

- (1) No Federally appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a member of Congress, an officer or employee

of Congress, or an employee of a member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, and the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

- (2) If any funds other than Federally appropriated funds have been paid, or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of Congress, or an employee of a member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit SFLLL (Disclosure of Lobbying Activities), in accordance with its instructions.
- (3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 1352 USC 31. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

B. Representations

All extramural applicants are required to complete the representations below and submit with each application. The form for completion and submission is posted in eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). Upload the form into Grants.gov under Attachments.

Representations Regarding Unpaid Federal Tax Liabilities and Conviction of Felony Criminal Violations Under Any Federal Law

At the time of application submission, the applicant organization represents that it:

- (1) Is _____ Is not _____ a Corporation (“Corporation” means any entity, including any institution of higher education, other non-profit organization, or for-profit entity that has filed articles of incorporation). If the organization is a corporation, complete (2) and (3) below.
- (2) Is _____ Is not _____ a Corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.

- (3) Is ___ Is not _____ a Corporation that was convicted of a criminal violation under any Federal law within the preceding 24 months.

NOTE: If the applicant organization responds in the affirmative to either (2) or (3) of the above representations, the applicant is ineligible to receive an award unless the agency suspension and debarment official has considered suspension or debarment and determined that further action is not required to protect the Government's interests. The applicant organization therefore will be required to provide information about its tax liability and/or conviction, upon request, to the Grants Officer, to facilitate completion of the required consideration before award decisions are made.

In accordance with DoD appropriations, the following representation is required. The applicant, by its signature on the SF424, represents:

Representation Regarding the Prohibition on Using Funds Under Grants and Cooperative Agreements with Entities That Require Certain Internal Confidentiality Agreements.

By submission of its application, the applicant represents that it does not require any of its employees, contractors, or subrecipients seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting those employees, contractors, or subrecipients from lawfully reporting that waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information. Note that (1) the basis for this representation is a prohibition in Section 743 of the Financial Services and General Government Appropriations Act, 2015 (Division E of the Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113-235) and any successor provision of law on making funds available through grants and cooperative agreements to entities with certain internal confidentiality agreements or statements; and (2) Section 743 states that it does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

C. National Policy Requirements

The recipient must comply with the following requirements, as applicable. The full text of National Policy Requirements is available at <https://usamraa.health.mil/Pages/Resources.aspx>. Awards will incorporate the most recent set of National Policy Requirements available at the time of award.

Reporting:

1) FINANCIAL REPORTING

- a) Interim Federal Financial Report (SF 425) shall be submitted within 30 days following the end of each calendar quarter and must include in the remarks the location of financial

records and a point of contact for the Government to obtain access to the financial records associated with this award. The following reporting period end dates shall be used for interim reports: 3/31, 6/30, 9/30, and 12/31.

- b) Final Federal Financial Report (SF 425) is required within 120 calendar days of the completion date for the term of this award and must include in the remarks the location of financial records and a point of contact for the Government to obtain access to the financial records associated with this award.

2) QUARTERLY REPORT

- a) Quarterly reports are required and must be prepared in accordance with the Research Performance Progress Report (RPPR). The RPPR is the uniform format for reporting performance progress on Federally-funded research projects and research-related activities. For each year of the award, you must submit Quarterly Technical Progress Reports covering research results (positive and negative data) over a three-month period (quarter). A reporting quarter begins with the start date of the award and restarts annually from that date for the entire period of performance. A Quarterly Technical Progress Report for the fourth quarter each year is not required, as the Annual Technical Report must incorporate all four quarters of progress.
- b) Each report must be submitted electronically, within 30 days after the end of each quarter.

3) ANNUAL REPORT

- a) Annual reports are required and must be prepared in accordance with the Research Performance Progress Report (RPPR). The RPPR is the uniform format for reporting performance progress on Federally-funded research projects and research-related activities. Annual reports must provide a complete summary of the research results (positive or negative) to date in direct alignment to the approved SOW. The importance of the report to decisions relating to continued support of the research cannot be over-emphasized.
- b) An annual technical report must be submitted within 30 calendar days of the anniversary date of the award for the preceding 12-month period.

4) FINAL TECHNICAL REPORT

- a) Within 120 calendar days of completion or termination of this Agreement, the Recipient shall submit a Final Report addressing the technical achievements of the program. The report should provide a synopsis of the accomplishments made under the Agreement. No proprietary or classified information shall be included in the final report as it is subject to public release.

4) OTHER

In addition to quarterly, annual and a final report, in-person presentations may be requested.

The Award terms and Conditions will specify if more frequent or other special reporting is required.

Awards resulting from this Program Announcement will incorporate additional reporting

requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations.

G. Federal Awarding Agency Contacts

Questions regarding program policy, program content, or technical issues should be directed prior to:

- **DHA MHSR, Program Mailbox**
dha.ncr.j-9.mbx.hsr@health.mil
- **GRANTS.GOV Contact Center**
Questions related to proposal submission through the GRANTS.GOV portal should be directed to the GRANTS.GOV Contact Center, which is available 24 hours a day, 7 days a week (closed on US federal holidays).
Phone: 800-518-4726;
International: 1-606-545-5035
Email: **SUPPORT@GRANTS.GOV**

H. Other Information

The following internet addresses may help the applicant understand more about the funding opportunity and program initiatives.

MHSR Resources:

Applicants wishing to learn more about health system research delivery are encouraged to consult the following:

- **Academy Health** (<https://www.academyhealth.org/evidence>): The science of study that determines what works, for whom, at what cost, and under what circumstances. It studies how our health system works, how to support patients and providers in choosing the right care, and how to improve health through care delivery. This site offers additional information on health services research topics and provides additional resources.
- **Health Services Research Journal** (<http://www.hsr.org/>): The official journal for Academy Health and the flagship journal for Health Research & Education Trust is published six times a year.
- **Health Services Research & Public Health Information Programs** (<https://www.nlm.nih.gov/hsrph.html>): A free health services research and public health resource containing a research portal and database run by the National Information Center

on Health Services Research and Health Care Technology at the National Library of Medicine.

- **U.S. Department of Veterans Affairs Health Services Research & Development** (https://www.hsrd.research.va.gov/for_researchers/default.cfm): The Department of Veterans Affairs (VA) Health Services Research and Development Service (HSR&D) pursues research that underscores all aspects of VA healthcare: patient care, care delivery, health outcomes, cost, and quality. HSR&D research also addresses critical issues for veterans returning home from Iraq and Afghanistan with conditions that may require care over their lifetimes. Within VA HSR&D, researchers focus on identifying and evaluating innovative strategies that lead to accessible, high quality, cost-effective care for veterans and the nation.
- **VA/DoD Collaboration Guidebook for Healthcare Research** (<https://mrhc.health.mil/assets/docs/orp/VA-DoD-Guidebook-2013.pdf>): The purpose of this guidebook is to help facilitate collaborative human subject healthcare research between the VA and the DoD.
- **Agency for Healthcare Research and Quality (AHRQ)** (<https://www.ahrq.gov>) AHRQ is the Federal agency charged with improving the safety and quality of American's health care system.
- **Patient-Centered Outcomes Research Institute (PCORI)** (<https://www.pcori.org/>) PCORI funds research that offers patients and caregivers the information they need to make important health care decisions.

DoD Research Data Resources:

Applicants are encouraged to consider leveraging resources available through existing DoD and/or VA. These resources include:

- **Military Data Repository (MDR)** is a centralized data repository that captures, validates, integrates, distributes, and archives corporate health care data. The MDR and MHS Mart (M2) are the most comprehensive health care databases that provide the opportunity to study the impacts of universal access to care and has the potential to influence U.S. health care. (<https://www.health.mil/Military-Health-Topics/Technology/Support-Areas/MDR-M2-ICD-Functional-References-and-Specification-Documents>)
- **DaVINCI** is a database that combines DoD data with VA data to create a robust data platform for interagency collaboration and research on issues impacting those who were Active Duty. Information about DaVINCI is found at https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/2441-notes.pdf.
- **Defense Manpower Data Center (DMDC)** is a database that contains information regarding military personnel and their families for the purposes of health care, retirement funding and other administrative requirements. Information about DMDC can be found at: <https://www.dmdc.osd.mil/appj/dwp/index.jsp>.

- **Millennium Cohort Study (MCS)** and the Millennium Cohort Family Study together make up the Millennium Cohort Program (MCP) at the Naval Health Research Center, San Diego, CA. The MCS is the largest prospective health study in U.S. military history with approximately 200,000 participants. This is a prospective research study and database that examines the impact of military exposures and deployments on long-term health outcomes. Access to MCS data and bio-specimens requires collaboration with one of the MCS investigators and approval of the MCS oversight committee by way of a preproposal/proposal process. <http://millenniumcohort.org>
- **Soldier Performance, Health, and Readiness Database (SPHERE)** - The SPHERE Database is a high-resolution epidemiologic research tool that serves as a significant resource for identifying risk/protective factors and adverse health outcomes and for evaluating intervention strategies in Army personnel. The SPHERE is a vast data repository that combines US Army population data from multiple disparate Department of Defense agencies and is housed and managed within USARIEM's Military Performance Division by a team of epidemiologists, analysts, and database managers. <https://usariem.health.mil/index.cfm/research/divisions/mpd/sphere>
Point of Contact: usarmy.natick.medcom-usariem.mbx.usariem-sphere@health.mil

Multi-Institutional Research: A partnership with a DoD training installation or local academic institution or federal/national laboratory is allowed. Note, regardless of location, any work that is to be performed by associated non-DoD organizations must be limited to work performed under existing service contracts, under Cooperative Agreements, Cooperative Research and Development Agreement or Material Transfer Agreements. An awardee may, in accordance with his/her research project, use the funds to collaborate with Federal (DoD and non-DoD) and non-Federal entities to execute the research. If the proposed research is multi-institutional, plans for communication, funding, and data transfer between the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, must be included in the appropriate sections of the proposal. *A separate intellectual and material property plan agreed upon by all participating institutions is also required for multi-institutional research. A letter of support from an authorized representative of each respective organization must be enclosed with the submitted proposal.* Participating institutions must be willing to resolve potential intellectual and material property issues and to remove any barriers that may interfere with achieving high levels of cooperation to ensure successful completion of this award.

No proprietary information should be provided in the LOI. It is expected that proprietary information will be included in the proposal if selected. Proprietary information should be identified in the proposal by the applicant.

The government is not obligated to make any federal award because of the announcement. Only the Grants Officer can bind the federal government to the expenditure of funds.

I. APPENDIX

Statement of Substantial Involvement:

Substantial involvement means that the recipient can expect Federal programmatic collaboration or participation in carrying out the effort under the award. Examples of substantial involvement include:

- DOD participation on committees, such as steering committees and subcommittees, central to the activity
- DOD participation in protocol design or development
- DOD involvement in selection of contractors or other project staff
- DOD coordination or participation in data collection, analysis, and interpretation
- DOD coordination or provision of training of project staff in awardee institutions
- DOD participation in selection and approval of data analysis mechanisms
- DOD approval of a stage of a clinical trial or other collaborative project before the next stage starts
- DOD co-authoring papers
- DOD provision of resources, including contractors
- DOD involvement with management and technical performance

Recipient Responsibilities

The Recipient is responsible for:

- Performing the activities supported by this award, including providing the required personnel, facilities, equipment, supplies, and services
- Defining the approaches and plan, submitting the plans to the DHA MHSR Portfolio Manager for review, and incorporating DHA comments
- Managing and conducting project activities
- Providing all deliverables specified in the award on a timely basis
- Participating in all briefings specified in the award Project Objectives and attending and reporting project status at program/project review meetings as deemed necessary by the DHA Program Manager.
- Submitting technical reports to the DHA MHSR Program Manager and incorporating DHA comments.
- Presenting the project results at appropriate technical conferences or meetings as directed by the DHA MHSR Program Manager.
- Providing all knowledge products and results.

DHA Responsibilities

DHA is responsible for:

- Reviewing project plans, in a timely manner, and recommending alternate approaches to the work effort if the plans do not address critical Health Service Research issues.
- Suggesting specific direction or redirection of the work if duplication of efforts or interrelated activity is identified.

- Reviewing, in a timely manner, technical reports and other deliverables and providing comments to the Recipient.
- Conducting project and program review meetings to ensure adequate progress and that the work accomplishes the program and project objectives. Recommending alternate approaches to work or shifting work emphasis, if needed.
- Promoting and facilitating MHSR socialization, including disseminating program results through presentations and publications.
- Serving as a scientific/technical liaison between awardees and other program or industry staff.