# **NOTICE OF FUNDING OPPORTUNITY**

for the

**Department of Defense (DoD)** 

**Defense Health Agency (DHA)** 

Research and Development Directorate (J-9)

Military Health System Research (MHSR)

## **Table of Contents**

A.	Program Description	3
1.	MHS Description	3
2.	MHSR Priority Topic Areas	4
3.	Clinical Priority Areas	5
В.	Estimated Timeline for the Grants Process	5
C.	Federal Award Information	6
D.	Eligibility Information	6
1.	Eligible Applicants	6
2.	Number of Submission	7
3.	Other Infomration	7
E.	Application and Submission Information	
1.	Application Package	Error! Bookmark not defined.
2.	Content and Form of Application Submission	Error! Bookmark not defined.
3.	Submission Dates and Times	10
F.	Application Review Information	13
1.	Proposal Evaluation Criteria and Selection Information	13
2.	Scientific Technical Review	14
3.	Programmatic Review	14
G.	Federal Award Information	15
Н.	Federal Awarding Agency Contact(s)	15
I.	Other Information	15
1.	MHSR Resources:	16
2.	DoD Research Data Resources	16
J.	Proposal Submission Checklist	18
K.	Appendix: Statement Of Substantial Involvement	19
1.	Recipient Responsibilities	19
2.	DHA Responsibilities	20

#### 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 focused on the Quadruple Aim: improved health readiness, better health, better care, and lower cost.

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.

### 1. 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. (<a href="https://www.tricare.mil/Plans/Eligibility">https://www.tricare.mil/Plans/Eligibility</a>). 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 is comparable to the health maintenance organization benefits 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.

For further details on TRICARE plan options see: <a href="https://www.tricare.mil/Plans/HealthPlans">https://www.tricare.mil/Plans/HealthPlans</a>.

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

### 2. MHSR Priority Topic Areas

To be considered for funding, proposals must specifically address at least one of the **Priority Topic Areas** cited below and delineate how the research aims to address 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. The impact of standardizing clinical practice through clinical practice guidelines, evidence-based practices, and process improvements, on the health of the population/sub-population.

#### c. Outcomes -

Health outcome research identifies and measures the factors which impact a population of patients at the enterprise, geographic market level, or sub-population levels; examines the system level factors which influence achievement of the Quadruple Aim "better health" in comparison to private sector efforts. Health outcomes research incorporates clinical outcomes, financial impact, patient health, quality of life, and measurement of indicators that predict results important to patients and patient experience.

#### d. Variation -

Studies that examine the factors that influence unwarranted variation or differences in quality, utilization, cost, or outcomes within the MHS and the implications to the enterprise as a system of system of care.

#### e. Health Readiness -

Burden of disease and associated health and risk factors within 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 or structure of the MHS on health care cost, quality, utilization, health outcomes, manpower/staffing, or health care readiness. Comparisons to between direct and purchased care, or care within the private sector, and includes measurement of the impact of policy changes to the TRICARE benefit structure on utilization and cost.

### 3. Clinical Priority Areas

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

- a. Behavioral Health
- b. Neuro-musculoskeletal
- c. Primary Care
- d. Specialty Care
- e. Surgical Services
- f. Women and Infant
- g. Telehealth

Proposals must address one or more of the MHSR priority topic areas and one of the clinical priority areas listed. Letters of Intent (LOIs) applicants that do not meet this requirement will not be asked to submit a full proposal.

#### B. ESTIMATED TIMELINE FOR THE GRANTS PROCESS

It is incumbent upon the award recipients to ensure they have the appropriate agreements (e.g., Memorandum of Agreement or MOAs) and vehicles for accepting and obligating the Research, Development, Test and Evaluation (RDT&E) funds of the Defense Health Program.

**General timeline** for this announcement is subject to change.

<ul> <li>February 10, 2023</li> </ul>	NOFO posted on https://www.grants.gov
<ul> <li>March 17, 2023</li> </ul>	Deadline for receipt of LOI (5 weeks)
<ul> <li>March 31, 2023</li> </ul>	Release of invitations to submit full proposals (2 weeks)
• June 16, 2023	Deadline for receipt of full proposals (11 weeks)
<ul> <li>August 18, 2023</li> </ul>	Completion of scientific and programmatic reviews (9 weeks)
<ul> <li>September 22, 2023</li> </ul>	Begin notification of grant award winners

#### C. FEDERAL AWARD INFORMATION

For FY 2023, the DHA Research and Engineering Directorate is seeking to award grants to several successful candidates by October 30, 2023, or when funds are available. Total available funds for grants under this notice are anticipated to be \$10,000,000 but are subject to availability of DHA funds in <u>FY 2024</u>. It is anticipated that several awards will result from this NOFO, which will include both extramural and intramural grant awards.

- Any eligible applicants (as detailed below) can submit one or two LOIs <u>but</u> only one LOI will be considered.
- 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, may elect to fund only part of any or all proposals, and may incrementally or fully fund any or all proposals under this NOFO.

This funding opportunity will result in grants. General guidance and procedures for proposal submission are described at <a href="www.grants.gov">www.grants.gov</a>. If an award results in a cooperative agreement, the government will have substantial involvement in the project as outlined in Appendix of this notice.

#### D. ELIGIBILITY INFORMATION

### 1. 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: <a href="https://www.doi.gov/pmb/eeo/doi-minority-serving-institutions-program">https://www.doi.gov/pmb/eeo/doi-minority-serving-institutions-program</a>.

- 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.

### 2. Number of Submissions

An eligible applicant may submit up to two LOIs for consideration, but only one (1) LOI may be selected from the submitting extramural and/or intramural organization 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. A full proposal from a DoD intramural applicant <u>must include a succession plan</u> 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.

#### 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 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 review.
  - Resubmission of the LOI or failure to submit a full proposal by the proposal deadline will result in immediate dismissal from further review.

#### E. APPLICATION AND SUBMISSION INFORMATION

### 1. 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. PIs whose LOI aligns with the stated program priority areas as demonstrated by clearly stated objectives, aims, and appropriate methods will then be <u>invited</u> 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:**

- 1) General Information Required (1 Page)
  - i. Project title to be used throughout the grant process
  - ii. Contact information:
    - 1. Principal Investigator (PI), including organization

- 2. DoD affiliation, if any,
- 3. 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.
- iii. If the proposal is from an MSI, clearly state the investigator's institutional status within the MSI.
- iv. 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).
  - 1. Provide a brief description of the primary institution and facility where the research is expected to be performed.
  - 2. 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)

- 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).
- ii. 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) Narrative (5-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 <u>briefly</u> 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 addresses, why it was chosen, and who it will impact. Include:
  - 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, the extent to which the study could impact healthcare research, improve military health care, or promote the Quadruple Aim. 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.

#### **Full Proposal Content Requirement:**

- 1) All full proposals must be submitted through the website: <a href="https://www.grants.gov">https://www.grants.gov</a>. Proposals will not be accepted by mail or in person. Uninvited proposals will not be reviewed or considered for an award.
- 2) For this funding opportunity, each proposal submission must include the complete proposal package requirements established at <a href="https://www.grants.gov">https://www.grants.gov</a>. The completed proposal package shall be submitted by the AOR. Proposals should use Calibri 11 with one inch left and right margins and top and bottom margins.
- **3)** The proposal package includes the following **mandatory** components:
  - SF-424 Research and Related (R&R) Application for Federal Assistance Form
  - ii. R&R Other Project Information Form
    - a. Project Summary/Abstract Technical and a Lay Abstract
    - b. Project Narrative detailed methodology description
    - c. Bibliography & References Cited
    - d. Facilities & Other Resources
    - e. Equipment

- iii. Project/Performance Site Location
- iv. R&R Personal Data Form
  - a. R&R Senior/Key Person Profile (Expanded) Form PI(s) and Key Personnel Biographical Sketches (five-page limit per individual):

    Upload file as "Biosketch\_LastName.pdf." The NIH Biographical Sketch (non-fellowship) may be used

    (<a href="https://grants.nih.gov/grants/forms/biosketch.htm">https://grants.nih.gov/grants/forms/biosketch.htm</a>). 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.
- v. R&R Attachments
- vi. R&R Multi-Year Budget Form for years one and two
- vii. R&R Sub-Award Budget Attachment Form
  - a. See General Submission Instructions for more information about each form. All forms can be found on <a href="https://www.grants.gov">https://www.grants.gov</a>.
- viii. Other Notices:
- ix. 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 its 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.
- x. 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

a. LOI Submissions

All LOIs must be submitted by the PI through the DHA MHSR program mailbox (<a href="mailto:dha.ncr.j-9.mbx.hsr@health.mil">dha.ncr.j-9.mbx.hsr@health.mil</a>) by 17 March 2023, 5 PM EST. PIs and organizations identified in the LOI <a href="mailto:must">must</a> 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 (<a href="mailto:dha.ncr.j-9.mbx.hsr@health.mil">dha.ncr.j-9.mbx.hsr@health.mil</a>). A change in PI or organization after submission of the LOI will be allowed only at the discretion of the J-9 Technical Representative.

- **b.** Proposal Submissions
  - 1. All full proposal submissions must be submitted to <a href="https://www.grants.gov">https://www.grants.gov</a> by **16 June 2023, 5 PM EST**.
  - 2. The LOI and full proposal submission process should be started early to avoid missing deadlines, which will result in proposal rejection.
  - 3. There will be no grace periods. Applicants must be familiar with requirements from <a href="https://www.grants.gov">https://www.grants.gov</a>, including the need for an active SAM registration and an UEI as a Data Universal Numbering System is being phased out.
- c. LOIs/Proposals Rejections. LOIs or Proposals may be rejected due to any of the following:
  - 1. LOI Narrative is missing.
  - 2. LOI Narrative exceeds page limit.
  - 3. LOI was submitted by an ineligible organization.
  - 4. Submission of a proposal for which a LOI was not received.
  - 5. Submission of an approved LOI in lieu of a full proposal.
  - 6. Project Narrative is missing.
  - 7. Budget is missing.
  - 8. 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.
  - 9. The proposal fails to conform to this NOFO description to the extent that appropriate review cannot be conducted.
  - 10. Total costs as shown on the DoD Military Budget Form exceed the maximum allowed by this funding opportunity.
  - 11. PI transition plan and command letters of support are missing.
  - 12. Inclusion of URLs, except for links in References Cited and Publication and/or Patent Abstract sections.
  - 13. Page size is larger than 8.5 inches x 11.0 inches. (Approximately 21.59 cm x 27.94 cm.)
  - 14. The PI does not meet the eligibility criteria.

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

- d. All applicants will receive an acknowledgment from <a href="www.grants.gov">www.grants.gov</a> upon receipt of LOI or <a href="proposal">proposal</a> submissions.
- **e.** The following funding restrictions apply:
  - 1. The maximum period of performance is two years.
  - 2. 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 budget will be approved by the government exceeding the stated total costs or using an indirect rate exceeding the organization's negotiated rate.

- 3. 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.
- 4. 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.
- 5. Regardless of the period of performance or number of collaborators proposed, the applicant may not exceed the maximum allowable total costs.
- f. 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.
  - It is expected that any contracted services and/or Interservice Support Agreements (ISA) from intramural agencies will NOT EXCEED 30% of the proposed total budget unless approved via waiver during the proposal submission process. Arriving at the 30% mark can be by year, combination of years, or all in one year, if it does not exceed the total budget in calculating the total costs or include donated/contributed personnel time.
  - 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 FY24 funding which will expire September 30<sup>th</sup>, 2025. The intramural organization must plan accordingly to execute all received funds before they expire.
  - Applicants must provide Letters of Organizational Support from the following:
    - 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 from DHA to each institution.
    - 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.
- 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.

Direct transfer of funds from the recipient to a federal agency is not allowed except under very limited circumstances. See <a href="https://www.grants.gov">www.grants.gov</a> for additional information on budget considerations for proposals involving federal agencies.

- For this award mechanism, direct costs may be requested for (not allinclusive):
  - Salary (federal salaries paid by the parent organization may not be reimbursable)
  - Contract support
  - Research supplies
  - Equipment
  - Research-related subject costs
  - Clinical research costs
  - Support for multidisciplinary collaborations, including travel
  - Travel costs for up to one investigator to travel to one scientific/technical meeting per year
  - Travel costs are intended for the PI or his/her designee only, justification must be provided if other personnel are included in the travel budget

#### F. APPLICATION REVIEW INFORMATION

### 1. 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 J-9 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

#### a. 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 considering its needs.
- 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.

#### **b. Criteria.** Full proposals will be evaluated according to the following criteria:

- Research Objectives
  - Research aims
- Theoretical Rationale
- Scientific Design and Methods
- Impact/Outcomes
- Personnel and Facilities
- Budget
- Succession Plan
- Proposal Clarity

### 3. Programmatic Review

- To make funding recommendations, programmatic reviewers will use the following criteria:
  - Ratings and evaluations of the peer reviewers (e.g., the scored scientific review)
  - Relevance to the mission of the MHS/DHA
  - Relative innovation and impact
  - Proposed project timelines
  - Open Source/License/Architecture
- 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.

#### G. FEDERAL AWARD INFORMATION

Once the successful applicants have been selected, they will be notified by the DHA Grants Office of their award. A notification letter will outline and address any Pre-Award costs and grant authorization to begin performance. Pre-Award monies spent will be at the non-federal entity's own risk. The notice of the federal award signed by the DHA Grants officer is the authorizing document.

See the General Submission Guidance for administrative and national policy requirements at <a href="https://www.grants.gov">www.grants.gov</a>

Reporting for this grant opportunity is as follows:

- Quarterly, annual, and final technical progress reports will be required.
- Reports are to include financial status, and dissemination and implementation plans.
- In addition to written progress reports, in-person presentations may be requested.

### H. FEDERAL AWARDING AGENCY CONTACT(S)

- DHA Acquisition (J-4) Contracting/Grants/Agreements Officer
   Mr. Nicholas R. Ceciliani
- DHA MHSRP Technical Representative

Dr. Diana M. Luan

- Please email all questions to the:
  - 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

#### I. OTHER INFORMATION

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

#### 1. MHSR Resources:

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

- Academy Health (<a href="https://www.academyhealth.org/evidence">https://www.academyhealth.org/evidence</a>): 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 (<a href="http://www.hsr.org/">http://www.hsr.org/</a>): 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
   (<a href="https://www.nlm.nih.gov/hsrph.html">https://www.nlm.nih.gov/hsrph.html</a>): 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 (<a href="https://www.hsrd.research.va.gov/for researchers/default.cfm">https://www.hsrd.research.va.gov/for researchers/default.cfm</a>): 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://mrdc.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) (<a href="https://www.ahrq.gov">https://www.ahrq.gov</a>)
   AHRQ is the Federal agency charged with improving the safety and quality of American's health care system.
- Patient-Centered Outcomes Research Institute (PCORI) (<a href="https://www.pcori.org/">https://www.pcori.org/</a>)
   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
  <a href="https://www.hsrd.research.va.gov/for\_researchers/cyber\_seminars/archives/2441-notes.pdf">https://www.hsrd.research.va.gov/for\_researchers/cyber\_seminars/archives/2441notes.pdf</a>.
- **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: <a href="https://www.dmdc.osd.mil/appj/dwp/index.jsp.">https://www.dmdc.osd.mil/appj/dwp/index.jsp.</a>
- 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. <a href="http://millenniumcohort.org">http://millenniumcohort.org</a>
  - 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.

# J. PROPOSAL SUBMISSION CHECKLIST\*

	Action	Page Limit	Completed				
	Letter of Intent						
	Letter of Intent (LOI) Template						
	LOI Narrative	5					
=	References Cited	1					
9	List of Abbreviations, Acronyms, and Symbols						
	Key Personnel Biographical Sketches	5 per individual					
Full Proposal							
	R&R SF 424 Form						
	R&R Other Project Information Form						
	Technical <u>and</u> Lay Abstracts: Upload attachment in step 7 with file name "Abstract-technical.pdf" and "Abstract-Lay.pdf".	1 page each					
	Project Narrative: Upload attachment in step 8 with file name "ProjectNarrative.pdf".	20					
les	Bibliography & References Cited: Upload attachment in step 9 with file name "BibRef.pdf".						
Full Proposal	Facilities and Other Resources: Upload attachment in step 10 with file name "Support.pdf".	None unless otherwise listed					
	R&R Attachment Form	listed					
	List of Abbreviations, Acronyms, and Symbols: Uploa Attachment 1 with file name "ListAbbr.pdf".						
	Statement of Work: Upload as Attachment 2 with file name "SOW.pdf."	2					
	Outcomes and Impact Statement: Upload as Attachment 3 with file name "Impact.pdf."	1					
sal	Data and Research Resource-Sharing Plan: Upload as Attachment 4 with file name "Sharing.pdf."	1					
Full Proposal	Conflicts of Interest: Upload as Attachment 5 with file name "COI.pdf".						
3	Data Management: Upload as Attachment 6 with file name "DataManage.pdf".						

	Post-Award Project Knowledge Transition Plan: Upload	3	
	as Attachment 7 with file name "Transition.pdf".		
	·		
	R&R Personal Data Form		
	R&R Senior/Key Person Profile (Expanded) Form		
	(Mandatory for external organizations)		
	Attach PI Biographical Sketch with file name	5	
	"Biosketch_LastName.pdf" to the appropriate field.		
	Attach PI Current & Pending Support with file name		
	"Support_LastName.pdf" to the appropriate field.		
	Attach Biographical Sketch with file name	5 pages	
	"Biosketch_LastName.pdf" for each senior/key person to	per	
	the appropriate field.	biographi	
		cal sketch	
	Attach Current & Pending Support		
	(Support_LastName.pdf) for each senior/key person to		
	the appropriate field.		
Full Proposal	R&R Budget Form		
odo	Upload attachments with file name:		
Pro	"Budget Step_LastName.pdf", where step is the		
≡	corresponding letter in the form and last name is the last		
ŭ.	name of the PI.		
	R&R Attachment:		
	Letter of Organizational Support for Military Partners:		
	Resource from Manager/Comptroller or appropriate		
	financial (If Applicable)		
	R&R Attachment:		
	Letter of Organizational Support for Military Partners:		
	MTF, Installation Commander or equivalent		
	Commanders/Directors (If Applicable)		

<sup>\*</sup> See updated information at: www.grants.gov

### K. APPENDIX: STATEMENT OF SUBSTANTIAL INVOLVEMENT

The following outlines the substantial involvement if award results in a cooperative agreement.

### 1. 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 Program
   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.

### 2. 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 specified kinds of 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.