## **NOTICE OF FUNDING OPPORTUNITY**

for the

**Department of Defense (DoD)** 

**Defense Health Agency (DHA)** 

Research and Engineering Directorate

Military Health System Research (MHSR)

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## A. MILITARY HEALTH SYSTEM RESEARCH PROGRAM

The Military Health System Research (MHSR) Program provides grants for priority areas directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD [HA]) and the Defense Health Agency (DHA). The objective of the MHSR grant is to foster research capability and capacity within the Military Health System (MHS) that supports the MHS transition to an integrated health system focused on the Quadruple Aim: improved health readiness, better health, better care, and lower cost.

The MHSR seeks studies on factors that affect the access, economics/cost, quality, variation, and outcomes of military health care delivery. This includes how policies, social factors, financing systems, organizational structures and processes, health technologies, and behaviors influence military health care delivery to DoD beneficiaries, e.g., individual Service members, families, communities, and populations.

The MHSR goal is to identify and further characterize the factors that influence the efficiency and effectiveness of MHS care delivery. Knowledge obtained from this research supports evidence-based policy and decision-making at the strategic and front-line levels. This Notice of Funding Opportunity (NOFO) seeks rigorous health system research through collaborations that have the potential to innovate military and civilian health care. The goal is also to enhance data-driven evidence that optimizes the MHS delivery of health care during peacetime and war, to include potential future conflicts, and the improvement of beneficiary health. This NOFO is intended to solicit Intramural and Extramural Military Health System Research proposals 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 9.5 million beneficiaries, which include Service members (Active and Reserve) and their families, retirees and their families, survivors, and certain former spouses (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 (U.S.) 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 U.S.), 424 ambulatory care and occupational health clinics (373 in the U.S.), 248 dental clinics (204 in U.S.), and 251 veterinary facilities (206 in U.S.). 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.

According to 2018 data, the MHS provided 103.9 million outpatient visits, 979.6 thousand inpatient admissions, delivered 107.1 thousand babies, and filled 115.6 million prescriptions to a spectrum of beneficiaries that include: Active Duty (1.38 M) and their family members (1.68 M), Guard/Reserve (0.19 M) and their family members (0.78 M), and retirees and their family members (5.49 M). Data

on the 9.5 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 the standard TRICARE Prime. TRICARE Select is a fee-for-service plan available within the U.S. through any TRICARE-authorized provider, where patient costs vary based on the sponsor's military status. The TFL plan 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: https://www.tricare.mil/Plans/HealthPlans.

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. Health System Reform

Research that assesses the impact of significant MHS changes in policy or structure, such as how consolidation under a single management structure affects health care utilization, quality, cost, health outcomes, manpower/staffing, health care readiness, and/or graduate medical, dental, and health education. The research also may include comparisons with the impacts of policy and structural changes within the private sector. The impact of policy changes also includes the introduction of co-pays, deductibles, and expansion of benefits.

#### b. Economics and Cost

Research on the factors that shape the MHS, drive demand and utilization, and influence cost in either TRICARE direct, or purchased-care systems. These factors include issues related to efficiency, effectiveness, value, and behavior in the production and consumption of health and health care. Costs, charges, expenditures, and the impact of technologies on care delivery and cost are considered. This research delineates value-based care within the MHS in both purchased and direct care. pre- and post-studies looking at difference in the structure of the TRICARE contract and the impact on patient care.

## c. Quality

Research that examines the degree to which health services for individuals and populations are safe, effective, patient-centered, timely, efficient, equitable, and result in an increased likelihood of improved health. Quality research also explores the impact of standardizing clinical practice through clinical practice guidelines, evidence-based practices, and process improvements to

include the use of technology and new treatment modalities (e.g. precision medicine, genetics, artificial intelligence, augmented/virtual reality) on the health of the population/sub-population.

#### d. Outcomes

Health outcomes research identifies and measures the relationship between treatments or interventions delivered, and the improvements in health care delivery that impact the achievement of the Quadruple Aim's "better health." The results of research conducted in specific geographic markets or sub-populations of the MHS are compared with 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.

#### e. Variation

Studies that examine the regional, facility, or Service differences in health care and unwarranted variation or differences in quality, utilization, cost, or outcomes within the MHS and the implications to the health of the population and the system of care.

#### f. Health Readiness

Studies examining burden of disease, associated health and risk factors within the MHS populations, and the potential impact to force readiness; to include implications of disease burden as an indicator of medical readiness, potential impact to staffing, network utilization, cost for direct care or purchased care, and potential comparisons between MHS and private sector in similar markets.

## 3. Clinical Priority Areas

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

- Behavioral Health
- Cardiovascular Care
- Complex Pediatrics
- Critical Care/Trauma
- Dental Care
- Military-specific Care / Pre- & Post-Deployment Care
- Neuromusculoskeletal Health
- Oncology
- Primary Care / Specialty Care
- Surgical Services
- Women and Infant Care

Letters of Intent (LOI) and subsequent full proposals from Principal Investigators (PIs) must address one or more of the MHSR priority topic areas, and at least one of the clinical priority areas listed. LOI applicants who do not meet this requirement (i.e., addressing at least one MHSR priority topic areas and at least one clinical priority area) will not be asked to submit a full proposal.

## B. ESTIMATED TIMELINE FOR THE GRANTS PROCESS

Award recipients must ensure they have the appropriate agreements (e.g., Memorandum of Agreement [MOA]), and the vehicles for accepting and obligating the Research, Development, Test and Evaluation (RDT&E) funds of the Defense Health Program (DHP).

General timeline (estimated) for this announcement is listed below, subject to change:

a.	April 4, 2022	NOFO posted on https://www.grants.gov
b.	May 3, 2022 (11:59 p.m. EST)	Deadline for receipt of LOI (4-5 weeks)
c.	May 16, 2022	Begin to release notice of either rejection or
		invitation to submit full proposals via e-mail
d.	July 12, 2022 (11:59 p.m. EST)	Deadline for receipt of full proposals (8 weeks)
e.	September 30, 2022	Completion of Scientific and Programmatic Review
f.	October 2022	Notification of PIs and institutions that submitted full
		proposals

## C. ELIGIBILITY

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

Any eligible applicant (as detailed below) can submit one or two LOIs, but only one LOI from the same PI will be considered.

Full proposals will only be accepted from eligible applicants who submitted an LOI and also 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 www.grants.gov. If an award results in a cooperative agreement, the government will have substantial involvement in the project as outlined in Appendix of this notice.

## 1. Eligible Applicants

LOIs and full proposals for this funding opportunity may be submitted by research investigators, uniformed or civilian staff who work for extramural non-DoD organizations, or intramural DoD organizations, as defined below.

**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 U.S.: 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.
- It is recommended that extramural organizations partner with DoD partners to improve understanding of the context of the research.
- DHA encourages applications from Minority-Serving Institutions (MSI) that include Historically Black Colleges and Universities (HBCUs) and other institutions, as defined at: https://www.doi.gov/pmb/eeo/doi-minority-serving-institutions-program.
- **b. Intramural DoD Organization**: A facility or group of facilities owned, leased, or otherwise used by the 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 Military Treatment Facilities (MTFs), and/or DoD activities embedded within a civilian medical center.
  - A full proposal 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.
- c. Additional Information: For applicants with dual appointments with a Federal agency and a university, please identify the "single" organization or affiliation that will have legal authority over funds resulting from the award.
  - Government agencies within the U.S.: 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.
  - There is no cost-sharing or match requirement.
  - All partnership or contract agreements are the responsibility of the applicant's organization and should be in place prior to receiving the award of funds.

#### 2. Number of Submissions

An eligible applicant may submit up to two LOIs for consideration, but only <u>one</u> (1) LOI may be selected from the submitting extramural or intramural organization under this announcement. Full proposal submission is by invitation only and each applicant who submitted an LOI(s) and also received an invitation from MHSRP can only submit one (1) full proposal.

## D. LOI APPLICATION AND REVIEW

#### 1. The LOI Submission

The LOI application package must be e-mailed to: **dha.ncr.j-9.mbx.hsr@mail.mil**. All applicants will receive an email acknowledgment upon receipt of LOI submissions.

## 2. LOI Application Preparation

- a. All LOI documents must be prepared in either "Microsoft Word or "PDF."
- b. All LOI documents must have: "FY23 LOI", "LOI Short Title" and PI's last name & first name initial as a header on each page; failure to do so may cause a review delay or a rejection of the document altogether.
- c. A page number must appear on every page of the LOI documents.

#### 3. LOI Document Formats

- a. LOI package should have two separate files (either Microsoft Word or PDF):
  - 1) The LOI Narrative in one file (limit to 5 pages)
  - 2) All other LOI supportive documents in another single file
- b. The contents for narrative and supportive documents are described below.

#### 4. LOI Narrative

- a. The narrative is **limited to five (5) pages, which includes** text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, and drawings).
- b. The narrative should briefly describe the project.
- c. **Inclusion of URLs** in the narrative that provides additional information confer an unfair competitive advantage and, thus, are prohibited and **will result in rejection** of the LOI.
- d. No proprietary information should be provided in the LOI. It is expected that proprietary information will be included in the full proposal, if selected. The applicant should identify proprietary information in the proposal.
- e. The LOI Narrative should include the following:
  - 1) **Priority Topic Area**(s): Identify the FY 2023 DHA MHSR Priority Topic Area(s) that the proposed research addresses.
  - 2) **Alignment with Clinical Priority Areas**: Explain how the proposed research is relevant to the identified MHSR and the clinical priority areas, and supports the MHS.
  - 3) **Research Plan**: Briefly state the ideas and reasoning on which the proposed work is based:
    - 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.
    - 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).

- 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 other expected outcomes. For studies
  involving human subjects, include a description of the study population (size,
  distinctive characteristics, etc.). Include all data sources that require data-sharing
  agreements.
- Military Relevance and Impact: Describe, if successful, the extent to which the study could impact health care 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.
- **Timeline and Estimated Total Budget**: Provide the estimated total budget and a timeline to achieve the research plan. Sub-awards and contracts may not exceed 30 percent (%) of the total estimated budget.

## 5. LOI Supportive Documents

## a. General Information Requirements

- Contact information for the PI, including organization, DOD affiliation, if any, and 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.
- 2) If a proposal is from an MSI, clearly state the investigator's institutional status within the MSI in the LOI template.
- 3) 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.)
- 4) 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).
- 5) Collaborators and key personnel.
- 6) 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).
- 7) 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, including the expertise each brings to the proposed project. Explain how the team's expertise is appropriate and complementary for achieving the research goals. Also, briefly provide information on the primary institution and facility where the research is expected to be performed.

#### b. Supporting Documentation

1) **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).

- 2) **List Abbreviations, Acronyms, and Symbols**: Provide a list of abbreviations, acronyms, and symbols used.
- 3) 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.

## 6. LOI Review

- a. An MHSR LOI review committee will review all LOIs submitted:
  - 1) Pls whose LOI(s) best aligns with the stated priority areas, as demonstrated by clear objectives, aims, and appropriate methods, will then be invited to submit full proposals for consideration via a MHSR email.
  - 2) PIs whose LOI is not accepted by the LOI review committee for full proposal submission will be notified by an e-mail from MHSR Program.

## b. LOIs Rejections: LOIs 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) PI transition plan and command letters of support are missing.
- 5) Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- 6) The PI does not meet the eligibility criteria.

## E. FULL PROPOSAL APPLICATION AND REVIEW

## 1. Full Proposal Submission

- a. A Full proposal submission is by invitation only and each applicant who submitted an LOI(s) and also received an invitation from MHSRP can only submit one (1) full proposal.
- b. All full proposals must be submitted through the website: <a href="https://www.grants.gov">https://www.grants.gov</a> by / on required deadline.
- c. The completed proposal package shall be submitted by the AOR.
- d. The full proposals will not be accepted by e-mail, mail, or in-person.
- e. Uninvited proposals will not be reviewed or considered for an award.
- f. Each proposal submission must meet all proposal package requirements established at <a href="https://www.grants.gov">https://www.grants.gov</a>.
- g. There will be no grace periods.
- h. All applicants will receive an acknowledgment from www.grants.gov upon receipt of proposal submissions.

## 2. Mandatory Components

a. SF-424 Research and Related (R&R) Application for Federal Assistance Form

#### b. R&R Other Project Information Form

- 1) Project Summary/Abstract
- 2) Project Narrative
- 3) Bibliography & References Cited
- 4) Facilities & Other Resources
- 5) Equipment
- c. Project/Performance Site Location
- d. R&R Personal Data Form
- e. R&R Senior/Key Person Profile (Expanded) Form
- f. R&R Attachments
- g. R&R Multiyear Budget Form for years one and two
- h. R&R Sub-Award Budget Attachment Form
- i. Other forms as required, which can be found at www.grants.gov

## 3. Additional Requirements

#### a. Each applicant\* is required to:

- 1) Be registered in the System for Award Management (SAM) before submitting its application.
- 2) Provide a valid unique entity identifier (UEI) in its application.
- Continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency.
- \* Unless the applicant is an individual or Federal awarding agency that is excepted from those requirements under 2 code 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).
- b. An award will not be made to an applicant until the applicant has complied with all applicable UEI and SAM requirements. If an applicant has not fully complied with the requirements by the time DHA is ready to grant an award, the DHA Grants Office may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis to grant an award to another qualified applicant/proposal.
- c. 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 is being phased out.

## 4. Full Proposals Rejections

The proposals may be rejected due to any of the following:

- a. Submission of a proposal for which an LOI was not received.
- b. Submission of a full proposal without a proposal submission invitation.
- c. Project Narrative is missing.
- d. Budget is missing.
- e. 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.

- f. The proposal fails to conform to this NOFO description to the extent that appropriate review cannot be conducted.
- g. Total costs as shown on the DoD Military Budget Form exceed the maximum allowed by this funding opportunity.
- h. PI transition plan and command letters of support are missing.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- j. Page size is larger than 8.5 inches x 11.0 inches (approx. 21.59 cm x 27.94 cm).
- k. The PI does not meet the eligibility requirements.

## 5. Funding Restrictions

## The following funding restrictions apply:

- a. The maximum period of performance is two years.
- b. 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.
- c. 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.
- d. 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.
- e. 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 executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent on appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers.
  - 1) It is expected that any contracted services and/or Interservice Support Agreements (ISA) from intramural agencies will NOT EXCEED 30 percent of the proposed total budget, unless approved via waiver during the proposal submission process. Arriving at the 30 percent mark can be by year, combination of years, or all in one year, as long as it does not exceed the total budget in calculating the total costs, or include donated/contributed personnel time.
  - 2) 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 FY 2022 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.
  - 3) 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.

- 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.
- Sub-awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., MIPR, FAD process, or ISA [DD form 1144]).
   Direct transfer of funds from the recipient to a Federal agency is not allowed, except under very limited circumstances. See www.grants.gov for additional information on budget considerations for proposals involving Federal agencies.
- g. For this award mechanism, direct costs may be requested for (not all-inclusive):
  - Salary, including contract personnel (Federal salaries paid by the parent organization may not be reimbursable)
  - 2) Research supplies
  - 3) Equipment
  - 4) Research-related subject costs
  - 5) Clinical research costs
  - 6) Support for multidisciplinary collaborations, including travel
  - 7) Travel costs for up to one investigator to travel to one scientific/technical meeting per year
  - 8) 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.

## 6. Full Proposal Review

#### a. All full proposals will be evaluated using a two-tier review process:

- 1) The first tier is a peer review or scientific review of proposals against established criteria for determining technical merit.
- 2) The second tier is a programmatic review that makes recommendations for funding to the DHA Research and Engineering Directorate and the OASD(HA), based on scientific and technical merit and 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.

## b. All review processes are conducted confidentially to maintain the integrity of the meritbased 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.
- 2) Violations of these prohibitions will result in rejection of the organization's proposal.
- 3) 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.

#### c. Scientific Technical Review

- 1) General
  - The scientific review will be conducted by a Scientific Review Committee.

- To determine scientific and technical merit, the evaluators will assess and grade/evaluate all full proposals according to the criteria below, but the government reserves the right to reconsider in light of 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.
- 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.
- Highly ranked, well-justified projects that address all of the requested proposal elements will receive higher ranking scores.

#### 2) Criteria: Full proposals will be evaluated according to the following criteria:

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

#### d. Programmatic Review

- 1) The programmatic review will be conducted by a Programmatic Review Committee.
- 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 criteria/considerations are not listed in any order of importance.

3) Other factors taken into consideration may include the critical nature of the project, alignment to DoD's initiative, and availability of funding.

## F. FEDERAL AWARD INFORMATION

## 1. Government Obligation

- The government is not obligated to make any Federal award as a result of the announcement.
- Grants will be awarded to organizations, not to individuals.
- This MHSR awards will be made to U.S. entities only.

## 2. Notification

- a. Once the successful applicants have been selected, they will be notified by the DHA Grants Office of their award.
- b. A notification letter will outline and address any Pre-Award costs, and grant authorization to begin performance.
- c. 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.
- d. The applicants whose proposal is not selected for MHSR funding will also be notified by the DHA Grants Office.

## 3. Reporting Requirements

- a. Quarterly, annual, and final technical progress reports will be required.
- b. Reports are to include financial status, and dissemination and implementation plans.
- c. In addition to written progress reports, in-person presentations may be requested.
- d. In the final report to the project closure, it is required to report:
  - The impacts on MHS based on the funded project accomplishments
  - All successes and policy changes resulted from the funded projects
  - Contingency plan if the project fails to transition
  - A list of accomplishments, to include conference abstracts presented, publications, and manuscripts submitted
- e. Any research abstract for scientific/medical conferences resulted from the MHSR funded project will be sent to <a href="mailto:dha.ncr.j-9.mbx.hsr@mail.mil">dha.ncr.j-9.mbx.hsr@mail.mil</a> PRIOR to the submission to the conference(s).
- f. Any research manuscript for peer-review journal publication **resulted from the MHSR funded project** will be sent to **dha.ncr.j-9.mbx.hsr@mail.mil PRIOR** to the submission to the journals.
- g. Copies of all abstracts presented to national, regional and military meetings/conferences and publications in peer-review scientific/medical journals.

## G. FEDERAL AWARDING AGENCY CONTACT(S)

DHA Acquisition (J-4) Grants Officer

Mr. Nicholas R. Ceciliani

• DHA MHSRP Technical Representative

Dr. Nereyda Sevilla

• Please e-mail all questions to the:

DHA MHSR, Program Mailbox dha.ncr.j-9.mbx.hsr@mail.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 U.S. Federal holidays).

Phone: 1-800-518-4726

E-mail: <u>SUPPORT@GRANTS.GOV</u>

## H. ADDITIONAL 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:

- AcademyHealth (<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 AcademyHealth 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 health care: 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.amedd.army.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.

## 2. 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 have 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 biospecimens 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
- Deployment Health Survey Data at the Psychological Health Center of Excellence brings together large datasets from the military for longitudinal analysis of health and psychological health issues that inform readiness. In collaboration with the Army Analytics Group Research Facilitation Lab, Person-Event Data Environment provides a virtual platform that integrates large limited datasets and provides a platform for research and analysis. Additional information can be found at:
   <a href="https://health.mil/Military-Health-Topics/Centers-of-Excellence/Psychological-Health-Center-of-Excellence">https://health.mil/Military-Health-Topics/Centers-of-Excellence/Psychological-Health-Center-of-Excellence</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 in order 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.

## I. APPENDIX

#### 1. Statement of Substantial Involvements

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

#### a. Recipient Responsibilities : The recipient is responsible for:

- 1) Performing the activities supported by this award, including providing the required personnel, facilities, equipment, supplies, and services
- 2) Defining the approaches and plan, submitting the plans to the DHA MHSR Program Manager for review, and incorporating DHA comments
- 3) Managing and conducting project activities
- 4) Providing all deliverables specified in the award on a timely basis
- 5) 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
- 6) Submitting technical reports to the DHA MHSR Program Manager and incorporating DHA comments
- 7) Presenting the project results at appropriate technical conferences or meetings as directed by the DHA MHSR Program Manager
- 8) Providing all knowledge products and results

#### b. DHA Responsibilities: DHA is responsible for:

- 1) 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
- 2) Suggesting specified kinds of direction or redirection of the work if duplication of efforts or interrelated activity is identified
- 3) Reviewing in a timely manner, technical reports and other deliverables and providing comments to the recipient
- 4) 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
- 5) Promoting and facilitating MHSR socialization, including disseminating program results through presentations and publications
- 6) Serving as a scientific/technical liaison between awardees and other program or industry staff

## 2. LOI Template:

Attached separately as attachment A: FY23 MHSR LOI Template

# 3. Attachment for DoD Grant Applications (supplemental to the instruction form <a href="https://www.grants.gov">www.grants.gov</a>)

Attached separately as attachment B: Certifications and Representations

## 4. Proposal Submission Checklist (in order)

	Action	Page Limit	Completed			
	Letter of Intent					
	Title of Proposal, PI name, and affiliated institution	1				
	Letter of Intent (LOI) Template					
	LOI Narrative	5				
=	References Cited	1				
9	List of Abbreviations, Acronyms, and Symbols	2				
	Key Personnel Biographical Sketches	5 per individual				
	Full Proposal					
	R&R SF 424 Form					
	R&R Other Project Information Form					
	Technical and Lay Abstracts: Upload attachment in step 7 with file name "Abstract.pdf".	1 page each				
	Project Narrative: Upload attachment in step 8 with file name "ProjectNarrative.pdf".	20				
oosal	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					
	List of Abbreviations, Acronyms, and Symbols: Upload as 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	
	Data and Research Resource-Sharing Plan: Upload as Attachment 4 with file name "Sharing.pdf."	1	
	Conflicts of Interest: Upload as Attachment 5 with file name "COI.pdf".		
	Data Management: Upload as Attachment 6 with file name "DataManage.pdf".		
	Post-Award Project Knowledge Transition Plan: Upload as Attachment 7 with file name "Transition.pdf".	3	
oosal	R&R Personal Data Form		
Full Proposal	R&R Senior/Key Person Profile (Expanded) Form (Mandatory for external organizations)		
Ē	Attach PI Biographical Sketch with file name "Biosketch_LastName.pdf" to the appropriate field.	5	
	Attach PI Current & Pending Support with file name "Support_LastName.pdf" to the appropriate field.		
	Attach Biographical Sketch with file name "Biosketch_LastName.pdf" for each senior/key person to the appropriate field.	5 pages per biographi cal sketch	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.		
sal	R&R Budget Form		
odo	Upload attachments with file name:		
Full Proposal	"Budget Step_LastName.pdf", where step is the		
교	corresponding letter in the form and last name is the last 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)		