

FUNDING OPPORTUNITY ANNOUNCEMENT

for the

Department of Defense (DoD)

Defense Health Agency (DHA)

Research and Development Directorate (J-9)

Health Services Research (HSR)

A. Program Description

The Health Services Research Initiative, established in FY 2019, provides intramural and extramural HSR in topic areas directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD (HA)). The intent of this initiative is to foster HSR capability within the Military Health System (MHS) by fostering research that supports the transition to an integrated health system focused on the quadruple aim – improved health readiness, better health, better care, and lower cost.

HSR studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and ultimately health and well-being (Academy Health, 2000). This research integrates epidemiologic, sociologic, economic and other analytic sciences to understand the relationships between need, demand, supply, use, and outcomes of health care.

The goal of HSR is to identify the factors which influence the delivery of care. Knowledge obtained from HSR supports evidence-based policy and leadership decision-making at both the strategic and front-line levels. As part of the organization construct, HSR results in a learning organization with the goal to decrease system variation in terms of cost, quality, outcome, and health readiness. This Funding Opportunity seeks rigorous HSR that supports and builds capability for the evolution of the MHS through collaboration and innovation.

Research funded through this Funding Opportunity is intended to benefit and inform military health care delivery with potential implications for civilian health care. The mission of the HSR is to enhance data-driven evidence that optimizes the MHS delivery of health care and improvement of beneficiary health. This announcement is intended to solicit both intramural and extramural health services research aligned with DHA priority research areas that support the MHS, which are enumerated below.

Health Services Research Award Priority Topic Areas

The MHS is one of America's largest and most complex health care systems that provides universal access to 9.5 million beneficiaries, Service members (Active and Guard/Reserve) and their families; as well as retirees,

their families, survivors, and certain former spouses (<https://www.tricare.mil>). The MHS is composed of 54 full-service hospitals and more than 377 clinics; located on military installations around the world. These facilities are subject to the same requirements for accreditation as other U.S. hospitals with demands to improve quality, safety, costs and outcomes; with the additional requirement to improve military medical readiness for 1.37 million Active Duty Service members. The National Defense Authorization Act for Fiscal Year 2017, Section 702, requires the consolidation of all Military Treatment Facilities (MTFs) under the DHA.

The MHS is supported by the TRICARE health care program for uniformed Service members, retirees, and their families, which provides comprehensive coverage to all beneficiaries. TRICARE brings together the military hospitals and clinics worldwide (often referred to as “direct care,” usually in military treatment facilities, or MTFs) with 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.

TRICARE has several different plans. TRICARE Prime is comparable to health maintenance organization (HMO) benefits offered in many areas. Each enrollee chooses or is assigned a primary care manager (PCM), a health care professional who is responsible for helping the patient manage his or her care, promoting preventive health services (e.g., routine exams and immunizations), and arranging for specialty provider services as indicated. TRICARE Prime’s point-of-service (POS) option permits enrollees to obtain care from TRICARE authorized providers other than the assigned PCM without a referral, but with deductibles and cost shares significantly higher than those under TRICARE Standard with TRICARE Select being an enrollment based, self-managed preferred provider network plan. Finally there is TRICARE for Life (TFL), the Medicare wraparound coverage for TRICARE-eligible beneficiaries who have Medicare as their primary health care coverage. In most instances, Medicare pays first, then TRICARE pays second. Most TRICARE health plans meet the requirements for minimum essential coverage under the Affordable Care Act. For more information see: <https://www.health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Health-Care-Program-Evaluation/Annual-Evaluation-of-the-TRICARE-Program>

According to 2017 data, the MHS provided 106.1 million outpatient visits and inpatient admissions of 1 million patients, delivered 110,394 babies, and filled 119.4 million prescriptions to a spectrum of beneficiaries that include: Active Duty (1.37 M) and their family members (1.71 M), Guard/Reserve (170 k) and their family members (750 k), and retirees and their family members (5.42 M). Data on the 9.5 million beneficiaries and the TRICARE health plan are captured in the Military Data Repository (MDR, <https://www.health.mil/Military-Health-Topics/Technology/Support-Areas/MDR-M2-ICD-Functional-References-and-Specification-Documents>), a centralized data repository that captures, validates, integrates distributes, and archives corporate health care data. The MDR is the most comprehensive health care database that provides the opportunity to study the impacts of universal access to care and has the potential to influence U.S. health care.

To be considered for funding, proposals must specifically address at least one of the HSR topic areas cited below. Each topic area addresses different HSR categories (e.g., economics, quality, outcomes, variation, health readiness), and the proposal must delineate how the research aims address the priority topic area(s). Related HSR topics may be considered dependent upon funding availability and topic.

Priority Topic Areas:

1. Health System Merger and Consolidation (NDAA 2017 sec. 702)-

The impact of the merger and consolidation of the health system under a single management structure on health care utilization, quality, cost, health outcomes, manpower/staffing, or health readiness; including potential comparisons to similar activities within the private sector.

2. Cost and Economics-

Research on the factors that shape the healthcare system, drive demand and utilization as well as influence cost in either Purchased Care or Direct Care systems; impact of FY 2017 changes to the TRICARE benefit structure on utilization and cost that includes the introduction of co-pays and deductibles and expansion of benefits..

3. Variation -

Studies that examine the variation in quality, utilization, cost or outcomes within the MHS and the implications to healthcare.

4. Health Readiness-

Burden of disease and associated health and risk factors within the MHS and/or geographic market. Implications of disease burden as an indicator of medical readiness; potential to impact staffing, network utilization, and cost for direct care and/or purchased care; potential comparisons to private sector in similar markets.

5. Outcomes -

Outcomes studies examining variation associated health and risk factors at the health system, and/or geographic market or sub-population levels of the MHS with comparisons to private sector efforts. The impact of standardizing clinical practice through clinical practice guidelines (CPG), evidence-based practices, and process improvements, on the health of the population/sub-population. Specifically in following subject areas:

- a. Behavioral/mental health
- b. Women, Infant, Children
- c. Neuromuscular skeletal
- d. Surgical services and oncology

B. Federal Award Information

For Fiscal Year (FY) 2019, the Defense Health Agency (DHA) Research, Development Directorate (J-9) is seeking to award to a number of successful candidates by 30 September 2019. Total available funds for grants under this announcement is capped at \$10,000,000. It is anticipated that several awards will result from this funding opportunity announcement.

- The funded amount and period of performance of each proposal selected for award may vary depending on the research area and the technical approach to be pursued by the investigator selected. The maximum period of performance is 2 years. The period of performance must begin prior to 30 Sep 2019.
- Full proposals will only be accepted by principal investigators who submit a Letter of Intent (LOI) and receive 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 awards under this Funding Opportunity Announcement (FOA). All awards are subject to the availability of funds.

This funding opportunity will result in grants and/or cooperative agreements. If an award results in a cooperative agreement the Government will have substantial involvement in the project as outlined in Appendix 2 of this announcement.

C. Eligibility Information

1. Eligible Applicants - Proposals for this Funding Opportunity may be submitted by intramural and extramural organizations, these terms are defined below. DHA encourages proposals from Minority Serving Institutions (MSI). Grants will not be awarded to individuals.

- **Intramural DoD Organization:** A facility or group of facilities owned, leased, or otherwise used by OSD, the Military Departments, the Defense Agencies, and all other organizational entities within the DoD towards research, development, or engineering by employees of the DoD to include DoD laboratories, DoD military treatment facilities, and/or DoD activities embedded within a civilian medical center.
- **Extramural Organization:** An eligible non-DoD organization. Examples of extramural organizations include academic institutions, nonprofit organizations, other Federal Government organization other than the DoD, and research institutes (not to include Federally Funded Research and Development Centers (FFRDCs)).
 - o Federally Funded Research and Development Centers (FFRDCs) are not eligible to directly receive awards under this FOA. However, teaming arrangements between FFRDCs and eligible organizations are allowed if permitted under the sponsoring agreement between the Federal Government and the specific FFRDC.
 - o Government Agencies within the United States: Local, State, and 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.

2. **Cost Sharing or Matching** – There is no cost sharing or match requirement.

3. **Other** – This funding opportunity will be a two-step process. LOIs will be subject to a general review to determine if the research aligns with DHA's priority research area and objectives. If selected, the candidate will be invited to submit a proposal for a technical merit review which includes both scientific and programmatic review.

Two LOIs will be accepted for consideration, but only one proposal application from the submitting extramural PI and organization will be allowed under this announcement.

Two LOIs will be accepted for consideration, but only one proposal application from the submitting intramural PI will be allowed under this announcement.

D. Application and Submission Information

1. Application Package - This announcement contains the information to be submitted for the LOI and how to submit an application through Grants.gov. See Appendix 3 for more information in submitting applications through Grants.gov.

2. Content and Form of Application Submission

Letter of Intent (LOI) Template Content

- **General Information**

- Provide contact information for the PI, including organization, DoD Affiliation, and succession plan.
 - If proposal is from a MSI, clearly state the investigator's institutional status as an MSI in the LOI template.
 - Provide the organization's resource manager/comptroller or equivalent Business Official and Authorized Organizational Representative (AOR) responsible for program administration. If selected, this person will be identified in Block 5 of the SF-424 form.
 - Select the performing organization (i.e., site at which the PI will perform the proposed work) and the organization (i.e., organization submitting on behalf of the PI).
 - It is recommended that PIs identify an Alternate Submitter in the event that assistance with LOI submission is needed.
- **Collaborators and Key Personnel**
 - Provide the name, organization, and role of all collaborators and key personnel associated with the proposal (including co-investigators, mentors, collaborators, consultants, and sub-recipients/sub-awardees) associated with the proposal.
 - Describe the role of the PI, co-PIs (if applicable), key personnel, sub-awards (if applicable), and consultants (if applicable) in 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 facility where the research is expected to be performed.
- **Narrative (5-page limit)** - The LOI page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to 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:

- **HSR Priority Topic Area(s):** Identify the FY19 DHA HSR Priority Topic Area(s) that the proposed research addresses.
- **Alignment with Priority Topic Areas:** Explain how the proposed research is relevant to the identified Priority Topic Area(s) and supports the MHS through HSR.
- **Research Plan:** State the ideas and reasoning on which the proposed work is based. State the project's hypotheses, specific aims, objectives, and the experimental approach/research methods.
 - **Background/Rationale:** 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 that of the PI or member(s) of the collaborating team.
 - **Hypothesis, Specific Aims, and Objectives:** State the proposed project's hypothesis and/or objectives and the specific aims/tasks of the proposed research. **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:** Describe the research approach and rationale for accomplishing the aims and objectives, with information on proposed methods and analysis/evaluation strategies. Describe how the proposed work and research will create and demonstrate, validate, or serve as a proof of concept to meet a specific Priority Research Area impacting policy and/or decision making. Include a brief description of research design, methods, and analysis/evaluation strategies, as well as materials anticipated to be used during

the research. 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 (DSA).

- **Military Relevance and Impact:** Describe, if successful, the extent to which the study could impact healthcare research, improve military healthcare, and promote the quadruple aims. Describe how the proposed study will directly or indirectly benefit military Service members and other beneficiaries.
- **Timeline and Estimated Total Budget:** Provide the estimated total budget and a timeline to achieve the research plan. Sub-awards and contracts may not be more than 30% of the total estimated budget.

- **Supporting Documentation**

- **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).
- **List Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used.
- **PI and Key Personnel Biographical Sketches (five-page limit per individual):** Upload as “Biosketch_LastName.pdf.” Bold or highlight publications relevant to the proposed project. The NIH Biographical Sketch (non-fellowship) may be used (<https://grants.nih.gov/grants/forms/biosketch.htm>). Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

If selected applicants will be required to submit a proposal through Grants.gov. Proposals will not be accepted by mail or in person. Any proposals that are submitted through Grants.gov and were not requested will not be reviewed or subject to an award.

Proposal Contents

1. Each proposal submission must include the completed proposal package provided in Grants.gov for this Funding Opportunity. The submissions package shall be submitted by the Authorized Organizational Representative.
2. The proposal package includes the following **mandatory** components (refer to the General Submission Instructions, Section III for additional information on proposal submission):
 - **SF-424 Research and Related (R&R) Application for Federal Assistance Form:** Refer to the General Submission Instructions, Section III, for detailed information.
 - **R&R Other Project Information Form**
 - Project Summary/Abstract
 - Project Narrative
 - Bibliography & References Cited
 - Facilities & Other Resources
 - Equipment
 - **R&R Attachments**
 - **R&R Personal Data Form**

- **R&R Senior/Key Person Profile (Expanded) Form** (*Mandatory for extramural organizations, suggested for intramural organizations*)
- **R&R Budget Period 1 Form**

See General Submission Instructions for more information about each form. All forms can be found on Grants.gov.

3. Each applicant (unless the applicant is an individual or Federal awarding agency that is excepted from those requirements under 2 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: (i) Be registered in the System for Award Management (SAM) before submitting its application; (ii) provide a valid unique entity identifier in its application; and (iii) 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. An award will not be made to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements and, if an applicant has not fully complied with the requirements by the time DHA is ready to make award, DHA and WHS 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.

4. Submission Dates and Times

Letter of Intent (LOI) Submissions

All LOI's must be submitted by the PI to the HSR Mailbox: dha.ncr.j-9.mbx.hsr@mail.mil by 12 July 2019, 12:00PM EST. PIs and organizations identified in the LOI should be the same as those intended for the subsequent proposal submission. If any changes are necessary after submission of the LOI, the PI must contact dha.ncr.j-9.mbx.hsr@mail.mil. A change in PI or organization after submission of the LOI will be allowed only at the discretion of the Grants Officer.

Proposal Submissions

All proposal submissions must be submitted to Grants.gov by 23 Aug 2019, 12:00PM EST.

The LOI and full proposal submission process should be started early to avoid missing deadlines, which will result in proposal rejection. **There are no grace periods, nor will there be.** Applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number.

Proposals may be rejected due to the following:

- LOI Narrative is missing.
- LOI Narrative exceeds page limit.
- LOI was submitted by an ineligible organization
- Submission of a proposal for which a letter of invitation was not received.
- Project Narrative is missing.
- Budget is missing.
- 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.

- The proposal fails to conform to this Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Total costs as shown on the DoD Military Budget Form exceed the maximum allowed by this Funding Opportunity. (applies to intramural organizations)
- Letters of support are missing.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- The PI does not meet the eligibility criteria.
- Sections exceeding the specified page limits will have any pages after the limit removed before review.
- Documents not requested will be removed.

All applicants will receive an acknowledgment from the grant office of receiving submissions.

This announcement is not subject to Executive Order 12372, “Intergovernmental Review of Federal Programs”. Refer to the General Submission Instructions for budget regulations and restrictions for the Research & Related Budget. For all Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in the General Submission Instructions.

The following funding restrictions apply below.

- The maximum period of performance is 2 years.
- The anticipated **total** costs (direct and indirect) should budget 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.
- All direct and indirect costs of any sub-award (sub-grant or sub-contract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 2 years.
- Regardless of the period of performance or number of collaborators proposed, the applicant may not exceed the maximum allowable total costs.
- 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 upon appropriate safety and administrative approvals. 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 proposal submission process. Arriving at the 30% 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, 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 FY 19 funds will be obligated by 30 Sep 2019. The plan must include the funding mechanism(s) and contractual arrangements that will be used to carry over funds between fiscal years, if applicable.
 - 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. Refer to the General Submission Instructions, Section III.A.5. Research & Related Budget, for additional information on budget considerations for proposals involving Federal agencies.

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)
- 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.

E. Application Review Information

A. Proposal Evaluation Criteria and Selection information

All 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) technical merit and (b) the relevance to the mission of the HA/DHA and the MHS quadruple aims. The highest-scoring 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.

1. Scientific Review:

To determine technical merit, the evaluators' present intent is to evaluate Full Proposals according to the following criteria, 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 priority areas, listed above in the Program Description. Proposals will be scored and ranked based on how well each proposal addresses the

program priority areas and the requested elements listed in the Application and Submission section above. High priority, well justified projects that address all of the requested proposal elements will receive higher scores.

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

2. 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)
- Open Source/License/Architecture
- Relevance to the mission of the DHA J-9 HSR
- Relative innovation and impact
- Proposed project timelines

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.

E. Federal Award Information

Once the successful applicant has been selected they will be notified by the Grants Office (Washington Headquarters Services) of their award. A Letter of Intent which will outline and address any Pre-Award costs, authorization to begin performance. As this will be at the non-Federal entity's own risk. The notice of the Federal award signed by the grants officer is the authorizing document.

See the General Submission Instructions for administrative and national policy requirements.

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 plan
- In addition to written progress reports, in-person presentations may be requested.

G. Federal Awarding Agency Contact(s)

Grant Office

Washington Headquarters Services, Acquisition Directorate (WHS/AD)
Kellie Buck, Grants Officer

Email: kellie.e.buck.civ@mail.mil

DHA HSR, 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: 800-518-4726; International: 1-606-545-5035

Email: **SUPPORT@GRANTS.GOV**

H. Other Information

This is a new program initiative and is expected to focus on the priority areas and award more grants in the future.

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

HSR Resources: Applicants wishing to learn more about HSR are encouraged to consult the following:

- **AcademyHealth** (<https://www.academyhealth.org/evidence>): HSR, put simply, is 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 HSR topics and provides additional resources.
- **Health Services Research Journal** (<http://www.hsr.org/>): An official journal for AcademyHealth and the flagship journal for Health Research & Education Trust (HRET) is published 6 times a year
- **Health Services Research & Public Health Information Programs** (<https://www.nlm.nih.gov/hsrph.html>): A free HSR and Public Health resource containing a research portal and database for HSR run by the National Information Center on Health Services Research and Health Care Technology at the National Library of Medicine (NLM).
- **U.S. Department of Veterans Affairs Health Services Research & Development** (https://www.hsrd.research.va.gov/for_researchers/default.cfm): The 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** (http://www.ncdsv.org/images/VA-DOD_ResearchCollaborationGuidebook_2011.pdf) - The purpose of this guidebook is to help facilitate collaborative human subject healthcare research between the Department of Veterans Affairs (VA) and the Department of Defense (DoD).

Research Resources: Applicants are encouraged to consider leveraging resources available through existing DoD and/or Department of Veterans Affairs (VA) resources, if retrospectively collected human anatomical substances and correlated data are relevant to the proposed research. These resources include:

- **DoD Serum Repository** ([Armed-Forces-Health-Surveillance-Branch/Data-Management-and-Technical-Support/Department-of-Defense-Serum-Repository](#)): The DoD Serum Repository (DoDSR) was established in 1989 as the Army/Navy Serum Repository for storing serum that remained following mandatory HIV testing within the active and reserve components of the Army, Navy, and Marines. Since that time, the mission of the DoDSR has expanded to include the collection and storage of operational deployment specimens as well as Air Force specimens. Specimens contained in the DoDSR are available to researchers and other investigators within the DoD for the purposes of conducting militarily relevant investigations.
- **Millennium Cohort Program** (<http://millenniumcohort.org>): The 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, and has approximately 200,000 participants. The purpose of the MCS is to evaluate the impact of military experiences, including deployment, on long-term health outcomes of Service members, and to provide strategic policy recommendations that inform leadership and guide interventions. The MCS provides the DoD with unique data capabilities given the ability to: collect data via survey that is not collected elsewhere; to assess temporal sequence of exposures and outcomes or disease; to track Service members after they leave military service; and to link survey data with other enterprise data sources. 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.
- **Million Veteran Program** (<http://www.research.va.gov/MVP/default.cfm>): The VA's Million Veteran Program (MVP), with over 445,000 enrolled veterans, 32 percent of whom have reported a cancer diagnosis, provides a potential rich clinical database for genetic exploration and analyses.
- **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, CRADAs, 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.

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 as a result of the announcement. Only the grant officer can bind the Federal Government to the expenditure of funds.

PROPOSAL SUBMISSION CHECKLIST

	Action	Page Limit	Completed
	Letter of Intent		
LOI	Letter of Intent (LOI) Template		
	LOI Narrative	5	
	References Cited	1	
	List of Abbreviations, Acronyms, and Symbols		
	Key Personnel Biographical Sketches	5 per individual	
	Full Proposal		
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	

Full Proposal	Bibliography & References Cited: Upload attachment in step 9 with file name "BibRef.pdf".		
	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	
	R&R Personal Data Form		
	R&R Senior/Key Person Profile (Expanded) Form (Mandatory for external organizations)		
	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.		

Full Proposal	Attach Biographical Sketch with file name “Biosketch_LastName.pdf” for each senior/key person to the appropriate field.	5 pages per biographical sketch	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.		
	R&R Budget Form Upload necessary attachments with file name “Budget Step_LastName.pdf”, where step is the corresponding letter in the form and last name is the last name of the PI.		
	R & R Sub-award Budget Attachment(s) Form (if applicable)		
	R&R Project/Performance Site Location(s) Form (if applicable)		
	R&R Grants.gov Lobbying Form (if applicable)		
	R&R Disclosure of Lobbying Activities (SF-LLL) Form (if applicable)		

APPENDIX 1

GENERAL SUBMISSION GUIDE

A. Proposal Contents

5. Each proposal submission must include the completed proposal package provided in Grants.gov for this Funding Opportunity. The submissions package shall be submitted by the Authorized Organizational Representative.
6. The proposal package includes the following **mandatory** components
 - o **SF-424 Research and Related (R&R) Application for Federal Assistance Form:**
 - o **R&R Other Project Information Form**
 - Project Summary/Abstract
 - Project Narrative
 - Bibliography & References Cited
 - Facilities & Other Resources
 - Equipment
 - o **R&R Attachments**
 - o **R&R Personal Data Form**
 - o **R&R Senior/Key Person Profile (Expanded) Form (*Mandatory for extramural organizations, suggested for intramural organizations*)**
 - o **R&R Budget Period 1 Form**

Upload as “Abstract.pdf”.

This will be Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Use the outline below. Abstracts of all funded proposals will be posted publicly; ***therefore, proprietary information should not be included in the abstracts.***

Combine the technical and lay abstract into the same document starting each on a separate page.

- o **Technical Abstract (one-page limit):**
 - o **Background:** State the ideas and theoretical reasoning behind the proposed work.
 - o **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
 - o **Specific Aims/Milestones:** State the specific aims/milestones of the project.
 - o **Project Design:** Describe the project design.
 - o **Relevance:** Explain the potential relevance of the proposed work to the HSR Topic Area(s) being addressed and its impact on the quadruple aim.

- o **Impact:** Explain the potential impact of the proposed work to advancing the quadruple aim.
- o **Lay Abstract (one-page limit):**
 - o Lay abstracts should be written using the following outline, in a manner that readers without a background in science or medicine can readily understand and without repeating the technical abstract.
 - o Describe the objectives and rationale for the proposal.
 - o Describe the applicability and potential impact of the research.
 - What types of patients will it help, and how will it help them? Include the current available statistics to the related injury/condition.
 - What are the potential changes to cost, quality, outcomes, etc.?
 - What is the projected timeline to achieve the expected outcome?
 - o Describe how the proposed project will benefit the quadruple aim.
- **R&R Other Project Information 8: Project Narrative (20-page limit)**
Upload as “ProjectNarrative.pdf”.

The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to 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 proposal. However, URLs can be used in citations for relevant publications and patent abstracts.

Describe the proposed project using the outline below.

- o **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations or preliminary data on the proposed technical solution(s) and how they may have been utilized in similar environment(s). Describe previous experience most pertinent to this project. Any preliminary data should be from the laboratory of the PI or member(s) of the collaborating team.
- o **Hypotheses/Objectives:** State the hypotheses or research/evaluation questions and overall objective(s) to be reached.
- o **Specific Aims:** Concisely explain the specific aims to include expected timeframe of each aim. If this proposal is part of a larger study, present only tasks this award would fund.
- o **Project Design:** Describe the research design, methods, and analyses/evaluations in sufficient detail for analysis.
 - Support the choice of study variables/metrics.
 - Explain the basis for the research questions and/or study hypotheses.
 - Establish the relevance of the study and explain the applicability of the proposed findings.
 - Provide a detailed protocol including, but not limited to, proposed methodologies, research/test plan(s) and criteria, intended medical domain(s) or discipline(s), control groups, and defined statistical models.

- Define the study variables (independent/dependent) and define how they will be measured. Include a description of appropriate controls and the endpoints to be tested. Describe how data will be collected and analyzed in a manner consistent with the study objectives.
- Describe a plan for data access and outcome dissemination.
- For development of devices and technologies, discuss the engineering/technical design that will be used to achieve the project goals, demonstrating the feasibility of the proposed product development. Discuss engineering/design strengths and weaknesses and recommendations for overcoming/preventing them.
- Address all potential barriers
- Provide plans for addressing potential delays, unexpected events, changes in key personnel, and ongoing adaptation of the proposal. Provide a risk management plan to address barriers to plans. As relevant, describe plans for addressing potential issues unique to working within the MHS.
- Document the availability and accessibility of the study materials (including data) needed, as applicable.
- o **Project Milestones:** Identify timelines for critical events that must be accomplished in order for the project to be successful in terms of cost, schedule, and performance.
- o **Additional Information:** If human subjects are included in the research, proposals may be submitted without human and/or animal use protocols and institutional approvals. However, protocols with required institutional approvals must be submitted no later than 60 days after award to demonstrate continued progress and ensure continuation of payment. The Grants Officer may make exceptions in situations where human and/or animal use is not expected to begin until after the first year of the research project. In such cases, a timeframe for submission of the appropriate protocols and institutional approvals will be established before award.

PIs and collaborating organizations may not use, employ, or subcontract for the use of any human participants, including the use of human anatomical substances, human data, human cadavers, or laboratory animals until applicable regulatory documents are approved by the DHA.

- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
- Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.
- If applicable, indicate time required for submission and/or approval of documents (e.g., IRB, DSA).
- For studies involving human subjects, allow at least 2 to 3 months for regulatory review and approval by the DHA's IRB (via EIRB); this does not include the additional time required for local IRB review and approval.

- **R&R Other Project Information 9: Bibliography and References Cited**

Upload as a single file named “BibRef.pdf”.

If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; items not requested will be removed and may result in administrative withdrawal of the proposal.

List the references in the order they appear in the Project Narrative. Use a reference format that gives the title of the citation. Do not send or attach copies of articles in print. There is no form for this information. The attachments should be in PDF in accordance with the formatting guidelines specified for full proposal preparation.

- **R&R Other Project Information 10: Facilities and Other Resources:**

Combine and upload as a single file named “Support.pdf”. Start each document on a new page. ***There are no page limits for any of these components unless otherwise noted.***

If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used.

Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the proposal.

- o **Facilities:** Describe the facilities available for performance of the proposed request and any additional resources proposed for acquisition at no cost to the Government. Indicate if a Government-owned facility is proposed for use. Reference should be made to the original or present award under which the facilities or resources are now accountable. There is no form for this information. The attachments must be in PDF in accordance with the formatting guidelines outlined for full proposal preparation. **Note: For researchers who will require access to the Military Data Repository, a Data Use/Sharing Agreement must be put in place.**
- o **Publications and/or Patent Abstracts (five-document limit):** Include relevant publication citations (to include URLs) and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) can be attached.
- o **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. A letter for each organization involved in the project should be provided.
- o **Letters of Collaboration:** Provide letter(s) supporting stated collaborative efforts necessary for the project’s success, even if provided at no cost. ***If the project involves collaboration with a Military Facility (MHS facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center), special requirements apply.*** A collaborating DoD researcher must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the research project. This letter must be included with the proposal.

- o **Joint Sponsorship (if applicable):** Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal. In the absence of agreements among sponsors for joint support, the proposal should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal is submitted, information should be sent later as an addendum to the proposal. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship. Provide letters of support related to recruitment, subject access, and data access plans.
 - o **Equipment:** Describe existing equipment, and equipment to be obtained, for the proposed research project.
- **R&R Attachments (Upload into the “Attachments” form):**
 - o **Attachment 1: List of Abbreviations, Acronyms, and Symbols: Upload as “ListAbbr.pdf”.** Provide a list of abbreviations, acronyms, and symbols.
 - o **Attachment 2: Statement of Work (SOW) (two-page limit): Upload as “SOW.pdf”.** The SOW: outlines and establishes the submitter’s performance expectations; milestones for the work to be funded under this award; and establishes general objectives; sets specific goals and conditions for each year of the project; and the SOW for all award types will be incorporated into the award document and, as such, is subject to release under the Freedom of Information Act.
The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of step-by-step subtasks that relate to the major tasks and milestones within the period of performance. An outline should be included that shows the work statements to be accomplished in each year of the award. The SOW should describe only the work for which funding is being requested by this proposal and, as applicable, should also:
 - Include the following information for each study site/sub-award site: Organization; organization address; investigator(s), collaborator(s), consultant(s); description of research with animals, human anatomical substances, and/or human subjects or cadavers to be conducted at the site; and key personnel responsible for each major task and each subtask to be performed at the site.
 - Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. As applicable, estimated times to complete each task should include time for local and DHA regulatory review and approval, as shown below. Refer to Appendix 1 for additional information regarding regulatory review.
 - o For studies involving human subjects, include a subtask that allows at least 2 to 3 months for regulatory review and approval by the DHA IRB; this does not include the additional time required for local IRB review and approval.

➤ *The Government reserves the right to request a revised SOW format and/or additional information. This should include the areas described in the FOA.*

- o **Attachment 3: Outcomes and Impact Statement (two-page limit): Upload as “Impact.pdf”.** Explain in detail why the proposed research project is important, as follows:
 - o **Military Relevance:** Describe, if successful, the extent to which study could impact research and improve the quadruple aim. Describe how well the proposed study will directly or indirectly benefit military Service members and other beneficiaries.
 - o **Short-Term Impact:** Describe the anticipated outcome(s)/results(s)/theoretical framework, design, and/or plan that will be directly attributable to the proposed research.
 - o **Long-Term Impact:** Describe the anticipated long-term clinical/patient gains or improved health care processes from the proposed project. What is the indication and will the project transform the standard of care? Identify broader implications for the MHS.
 - o **Public Purpose:** If appropriate, provide a concise, detailed description on how this project will benefit the MHS and potentially the general public.
- o **Attachment 4: Data and Research Resource-Sharing Plan (one-page limit): Upload as “Sharing.pdf”.** Describe how unique and/or final research data will be shared with the MHS leadership and research community, along with any resulting research knowledge products. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed project. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data- and/or research resource-sharing plan.
- o **Attachment 5: Conflicts of Interest, if applicable: Upload as “COI.pdf”.** Provide details with the proposal submission of all potential or actual COIs, along with a plan to resolve or mitigate them. An assistance agreement will not be awarded if the respective Grants Officer determines that a COI cannot be mitigated to the Grants Officer’s satisfaction at his/her sole discretion or eliminated.
Personnel involved in the review process and/or with making funding recommendations are prohibited from assisting in any proposal, including, but not limited to, concept design, proposal development, budget preparation, and the development of any supporting documentation.

Questions related to this topic should be directed to the Grants Officer Kellie Buck, kellie.e.buck.civ@mail.mil.

- o **Attachment 6: Data Management (no page limit): Upload as “DataManage.pdf”.** The Data Management attachment should include the components listed below.
Data Management: Describe all methods used for data collection to include:

- o **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
- o **Confidentiality:** Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
 - Address who will have access to study records, data, and specimens, including an acknowledgment that DHA representatives are eligible to review study records.
 - Address requirements for reporting sensitive information to state or local authorities.
- o **Disposition of data:** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored. For FDA-regulated studies, acknowledge intent to comply with 21 CFR 11.
- o **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.
- o **Attachment 7: Post-Award Project Knowledge Transition Plan (three-page limit). Upload as “Transition.pdf”.** Provide information on the methods and strategies proposed to move the project or knowledge outcomes to the next project phase of studies, commercialization, and/or delivery to the civilian or military market after successful completion of the award. The transition plan should include the components listed below as applicable.
 - Details of the funding strategy that will be used to bring the outcomes to the next level of development and/or commercialization (e.g., specific potential industry partners, specific funding opportunities to be applied for).
 - A description of how the knowledge will be further developed, disseminated, and incorporated into clinical care and applicability to civilian health care.
 - A description of collaborations and other resources that will be used to provide continuity of development.
 - A schedule and milestones for bringing the outcome(s) to the next phase of studies.
 - A plan to communicate results and outcomes to relevant stakeholders.
- o **Attachment 8: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf”.** If a Military Facility will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form including a budget justification for each year. If more than one Military Facility is proposed, submit a separate budget form for each site.
- **R&R Personal Data**

This form will be used by DoD as the source of demographic information, such as gender, race, ethnicity, and disability information, for the Project Director (PD)/PI and all other persons identified as Co-PD(s)/Co-PI(s).

Each proposal must include this form with the name fields of the PD/PI and any Co-PD(s)/Co-PI(s) completed; however, provision of the demographic information in the form is voluntary. If completing the form for multiple individuals, each Co-PD/Co-PI can be added by selecting the “Next Person” button. The demographic information, if provided, will be used for statistical purposes only and will not be made available to merit reviewers. Applicants who do not wish to provide some or all of the information should check or select the “Do not wish to provide” option.

- **R&R Senior/Key Person Profile [(Expanded), **Mandatory for extramural organizations, suggested for intramural organizations**]**

- **DO NOT EXCEED 5 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.**

Include the following information for each person who will contribute significantly to the proposed research project or is otherwise identified as a key person.

- o **Biographical Sketch (5 pages each):** The NIH Biographical Sketch (non-fellowship) may be used (<https://grants.nih.gov/grants/forms/biosketch.htm>). Each biographical sketch must be in PDF format before attachment. Biographical Sketches should demonstrate background and expertise through education, positions, publications, and previous work accomplished. Include a Personal Statement and list all Research and Professional Experience.
 - **For Research and Processional Experience:** Concluding with present position, list in chronological order previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee(s). List in chronological order the titles, all authors, and complete references to all publications during the past 3 years and to representative earlier publications pertinent to this proposal. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. **PAGE LIMITATIONS APPLY.**
- o **PI Biographical Sketch: Upload as “Biosketch_LastName.pdf”,** where “Last Name” is the last name of the PI.
- o **Key Personnel Biographical Sketches: Upload as “Biosketch_LastName.pdf”,** where “Last Name” is the last name of the respective individual.
- o **PI Current & Pending Support: Upload as “Support_LastName.pdf”,** where “Last Name” is the last name of the PI.

For all previous (award period of performance ending within the past 5 years), current, and pending research support, include the title, time commitments, supporting agency, name and address of the funding agency’s procuring Grants Officer, period of performance, level of funding, brief description of the project’s goals, and list of the specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. If applicable, state that no overlap exists. If there is no previous, current, or pending support,

enter “None.” An updated previous, current, and pending support document will be required if an award is recommended for funding.

- o **Key Personnel Current & Pending Support: Upload file as “Support_LastName.pdf”**, where “Last Name” is the last name of the respective individual. Refer to content requirements under “PI Previous/Current/Pending Support” listed above.

B. Budget Regulations and Restrictions:

The following must be utilized in developing the budget:

- **Administrative and Cost Principles.** Awardees are required to comply with the following, as applicable:
 - o 2 CFR Part 200, “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards,” implemented by Chapter XI of Title 2, CFR.
- **Award Funding/Maximum Obligation:**
 - o **Assistance Agreement Awards:** Awards will not be modified to provide additional funds for such purposes as reimbursement for unrecovered indirect/facilities and administrative costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.
- **Pre-Award Costs:** Pre-award costs may be allowable as follows:
 - o **Assistance Agreement Awards:** An institution of higher education, hospital, or non-profit organization may, at its own risk and without the Federal Government’s prior approval, incur obligations and expenditures to cover costs up to 90 days before the start date of the period of performance, if such costs (1) are necessary to conduct the project; and (2) would be allowable under the award, if awarded, without the Government’s prior approval. If specific expenditures would otherwise require prior approval, the awardee must obtain the Grants Officer’s approval before incurring the costs. Government prior approval is required for any costs to be incurred more than 90 days before the start date of the period of performance. For-profit organizations must obtain the Grants Officer’s approval before incurring any obligations and expenditures before the start date of the period of performance. Reference 2 CFR 200.458.

For-profit organizations must obtain the Grants Officer’s approval before incurring any obligations and expenditures before the beginning date of the initial budget period of a new award. Reference 32 CFR 34.15.

The incurrence of pre-award costs imposes no obligation on the Government either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. The Federal Government expects the awardee to be fully aware that pre-award costs may result in borrowing against future support and that such borrowing

must not impair the organization's ability to accomplish the project objectives in the approved timeframe or in any way adversely affect the conduct of the project.

- **Cost of Preparing Proposals:** The cost of preparing proposals in response to the FOA is not considered an allowable direct charge to any resultant award. However, the cost of preparing proposals may be an allowable expense included in the indirect/facilities and administrative cost as specified in the organizations applicable cost principles.
- **Currency:** All costs must be entered in U.S. dollars. Recipients performing research outside of the United States should include the cost in local currency, the rate used for converting to U.S. dollars, and justification/basis for the conversion rate used. Foreign currency exchange rates for recipients performing research outside of the United States will be based on the official rate in effect at the time of submission.

Submit a detailed budget and justification that covers the entire period of performance (not just the first year). The Government reserves the right to request a revised budget and budget justification and/or additional information.

Budget Instructions: Complete the Research & Related Budget following the instructions below. Begin by entering the organizational DUNS number, Budget Type, Name of Organization, and anticipated start and end dates. ***Ensure that the DUNS number is entered accurately or Grants.gov will reject the proposal. For all Federal agencies or organizations collaborating with Military Facilities, special restrictions apply to the budget and are described below.***

For Federal Agencies (as applicant): A proposal from a Federal agency must include in the budget justification a **Federal Financial Plan (Plan)**. The Plan must address how all funds will be obligated before their period for obligation expires, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.

For Collaborating Military Facilities: A proposal from an extramural organization that includes collaboration with a Military Facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) must submit a Collaborating DoD Military Facility Budget Form(s). Include any Military Facility's direct and indirect costs on this form. Also, include the Military Facility's total costs (direct and indirect) on the Sub-award/Consortium/Contractual Costs line of the Research & Related Budget Form

(Section F.5.). See [Section III.A.9, Collaborating with DoD Military Facilities](#), for additional information.

Section A: Senior/Key Person

- **Prefix; First, Middle, and Last Name; and Suffix:** Beginning with the PI, list all senior/key persons from the applicant organization who will be involved in the proposed research project, whether or not salaries are requested. Include all investigators, research associates, etc. If applicable, all investigators outside the applicant organization should be

included on the R & R Sub-award Budget Attachment(s) Form. Consultant costs should be listed under Section F.3.

- **Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.
- **Base Salary:** Enter the current annual base salary (based on a full-time appointment) for each individual listed for the proposed research project. Establish labor costs using current labor rates or salaries. Labor rates or salaries may not be increased as a result of receiving an award. Identify and explain in the budget justification any proposed adjustments to rates or salaries. Any proposed increases in rates or salaries over the period of the award must be consistent with the applicable cost principles and organization's estimating procedures. ***For most Federal agencies, funding cannot be applied toward Federal salaries; therefore, these salaries should not be included in the requested budget.***
- **Calendar, Academic, and Summer Months:** For each senior/key person, including unpaid personnel, list the number of months to be devoted to the proposed research project in the appropriate box.
- **Requested Salary:** Enter the amount of salary requested for this budget period.
- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. If the proposal is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement or other policy document).
- **Funds Requested:** Enter the total funds requested for each senior/key person listed for the proposed research project.
- **Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.

Section B: Other Personnel

- **Number of Personnel:** For each project role category, indicate the number of personnel for the proposed research project, including unpaid personnel.
- **Project Role:** Identify each project role category. Within the budget justification, describe the specific functions of the personnel in each project role.
- **Calendar, Academic, and Summer Months:** For each project role category, list the number of months to be devoted to the proposed research project in the appropriate box.
- **Requested Salary:** Enter the amount of salary requested for this budget period. ***For most Federal agencies, funding cannot be applied toward Federal salaries; therefore, these salaries should not be included in the requested budget.***
- **Fringe Benefits:** Enter the fringe benefits requested for each project role category in accordance with organizational guidelines. If the proposal is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current DHHS Rate Agreement, other federally approved rate agreement, or other policy document).

- **Funds Requested:** Enter the total funds requested for each project role category listed for the proposed research project.

Section C: Equipment Description: Equipment is tangible personal property (including information technology systems) having a useful life of more than 1 year and a per unit acquisition cost of (a) \$5,000 or more per unit, or (b) the awardee's or sub-awardees' capitalization threshold for financial statement purposes. Applicant organizations are encouraged to provide all equipment necessary to conduct the proposed research project. If equipment is requested, provide a detailed list showing the cost of each item. The budget justification for any requested equipment must describe, as applicable:

- Special test equipment to be fabricated for specific research purposes and its cost.
- Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately.
- Existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the awardee with award funds, would be capitalized for Federal income tax purposes.

In addition, requests for equipment must include a rationale for estimated costs.

Section D: Travel: Travel costs may include:

- Costs to attend **one** scientific/technical meeting per year: Include the meeting name, purpose, location, and date, if known, in the budget justification. International travel may be requested but must be well justified and is subject to approval.
- Costs for travel required for the execution of the proposed work (if applicable): Reasonable costs for travel between collaborating organizations should be included. International travel may be requested but must be well justified and is subject to approval.

Section E: Participant/Trainee Support Costs: Enter the funds requested for tuition/fees, health insurance, stipends, travel, subsistence, and other costs.

Section F: Other Direct Costs

- **Materials and Supplies:** Supplies means all tangible personal property, including a computing device, acquired under an award that does not meet the definition of equipment. The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies for each year. For individual or total materials and supplies costing \$5,000 or more per year, provide additional breakdown.
Computers and software are considered to be general office supplies and are not normally allowable direct cost charges unless the computer/software is essential and unique to the proposed research project.

- If a computer/software purchase is requested, include the following in the budget justification:

- Detailed explanation for why purchase of computer/software is required to complete the proposed research project.
- Statement verifying that the requested computer/software is not currently available for use by the PI.
- Statement assuring that the requested computer/software will be purchased in accordance with applicable cost principles.
- **Publication Costs:** Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.
- **Consultant Services:** Regardless of whether funds are requested, include in the budget justification the names and organizational affiliations of all consultants, and include the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.
- **Automated Data Processing (ADP)/Computer Services:** Include the cost of computer services, including computer-based retrieval of scientific, technical, and education information. Include in the budget justification the provider's computer service rates.
- **Sub-award/Consortium/Contractual Costs:** Include the total funds (direct and indirect costs) requested for (1) all sub-award/consortium organization(s) proposed for the research project and (2) any other costs proposed for the research project. This amount should be supported in the sub-award/consortium/contractual costs provided in the R & R Sub-award Budget Attachment(s) Form.

If a Military Facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Budget Form, including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under sub-award costs.

See [Section III.A.9., Collaborating with DoD Military Facilities](#) below, for more information.

- **Equipment or Facility Rental/User Fees:** List proposed equipment or facility rental/user fees. Include appropriate information (hours and rates) in the budget justification.
- **Alterations and Renovations:** Alteration and renovation (A&R) costs can be requested if the costs are essential to accomplish the objectives of the research project and **are a minor portion of the overall budget**. A description of the existing facility and detailed description of the requested changes, along with a cost estimate, must be included in the budget justification. **Costs for the construction of facilities are not allowable.**
- **Other Expenses:** Itemize other anticipated direct costs such as communication costs and organizationally provided services. These items should be described in detail and clearly justified in the budget justification. Organizationally provided services should be supported by the organization's current cost/rate schedule.

For research involving human subjects, include itemized research-related subject costs for the proposed research project. These costs are strictly limited to expenses specifically associated with the proposed research project.

Section G: Direct Costs: Include the total direct costs (A-F).

Section H: Indirect Costs: The indirect costs category may include Facilities and Administrative (F&A) costs, overhead, General and Administrative (G&A), and other. The most recent Federal agency approved rate(s) should be applied. If the rate(s) has been approved by other than a Federal agency, indicate the source of the approval.

In accordance with 2 CFR 200.414, a non-Federal entity that has never received a negotiated indirect cost rate, may elect to charge a *de minimis* rate of 10% of modified total direct costs. If this methodology is chosen, it must be used consistently for all Federal awards until such time as the non-Federal entity chooses to negotiate for a rate. Costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both.

Provide details of the direct cost base (modified total direct costs, salary and wage, or other). Identify any costs that have been excluded from the base (in accordance with the approved rate agreement). Also indicate if the rate(s) is an on- or off-site rate(s). If more than one rate is applicable, provide a breakdown of the calculation.

Provide documentation to support the indirect cost rate (e.g., the current DHHS, Defense Contract Audit Agency [DCAA] or other federally approved rate agreement, or other policy document).

Organizations can also visit the DHHS (<https://rates.psc.gov/fms/dca/negotiations.html>), the ONR (<http://www.onr.navy.mil/Contracts-Grants/manage-grant/indirect-cost-proposal.aspx>), and the DCAA (<http://www.dcaa.mil/>) for additional information on indirect rates.

Section I: Total Direct and Indirect Costs: Include total costs for the proposed research project.

Section J: Fee: Charging a fee or profit to an assistance agreement, either by the recipient/awardee, sub-recipient/sub-awardee, is prohibited.

Section K: Budget Justification: Provide a clear budget justification for each year and for each item in the budget over the entire period of performance and attach as a single PDF file to Section K of the Research & Related Budget.

Proposals from **Federal agencies** must include in their budget justifications a **Federal Financial Plan**. The Plan must address how all funds will be obligated before their expiration for obligation, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.

➤ *Organizations must provide sufficient detail and justification to enable the Federal*

Government to determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

7. Project/Performance Site Location(s) Form

Indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. Add more sites as necessary using the “Next Site” button. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach it to this form. Each additional research site requesting funds will require a sub-award budget.

8. R & R Sub-award Budget Attachment(s) Form (if applicable)

Complete a separate detailed Research & Related Budget (direct and indirect costs) including a budget justification for each sub-award (sub-grant or subcontract) in accordance with the instructions listed above. Title each individual sub-award, “Research & Related Budget,” with the name of the sub-recipient/sub-awardee organization, and attach to the R & R Sub-award Budget Attachment(s) Form.

A description of services or materials that are to be provided under the sub-award is required. Organizations must provide sufficient detail and justification to enable the Federal Government to determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

If collaborating with a DoD Military Facility, do not complete this form; complete the Collaborating DoD Military Facility Budget Form. See [Section III.A.9, Collaborating with DoD Military Facilities](#).

9. Collaborating with DoD Military Facilities

This section addresses requirements and procedures when a Military Facility will be a collaborator in performance of an extramural project.

Budget Form: Complete a separate “**Collaborating DoD Military Facility Budget Form,**” for each Military Facility involved in the project. Do not complete the grants.gov R&R Sub-award Budget Attachment Form.

Direct Costs:

- **Salaries:** Include the positions/titles/ranks and levels of effort of all DoD civilian and military personnel expected to work on the extramural project, whether or not salaries/fringe benefits are proposed. Salaries/fringe benefits **may** be reimbursed, either directly by the Federal Government to the facility or through the extramural award to the facility, **but only under certain limited circumstances, which will be discussed during negotiations.** Extramural organizations may provide personnel to work at intramural DoD partnering organizations. The Extramural personnel costs should not be included here but on the organization’s Research and Related Budget Form.
- **Travel:** Include costs to be incurred by DoD civilian and military personnel. However, **note that these costs cannot be reimbursed through the extramural award.** They can

only be funded directly by the Federal Government to the facility. Some restrictions apply. Processes will be discussed during negotiations.

- **Consultants, Equipment, Materials, Supplies, Other, Etc.:** Include all anticipated direct costs. The Military Facility should consider whether the applicant organization can purchase the items/resources and provide them to the facility. The organization may provide resources to the Military Facility, such as consultants, supplies, equipment, etc., acquired with award funds. If this is feasible, these funds should be included on the applicant organization's Research & Related Budget Form and should not be included on this form. Title of all equipment will remain with the Government.
- **Rates/Fees (Other than Indirect Cost Rates and Profit):** Where there are no DoD-established reimbursement rates (e.g., Institutional Review Board [IRB] fees), the Military Facility's Resource Manager/Comptroller/Task Area Manager or equivalent Business Official must provide details of how the proposed rates/fees were determined. Rates/fees should be included in the Other Direct Costs line of the Research & Related Budget Form (Section F.8-10.).
- **Indirect Costs:** If an indirect cost rate is proposed, include documentation to support the rate (i.e., cost pool(s) and what items are included in each pool). The Military Facility should consult with its RM office (or equivalent) for assistance in determining a rate.
- **Total Costs:** Include the facility's combined direct and indirect costs. Enter the total here and also include it in the Sub-award/Consortium/Contractual Costs budget line on the Research & Related Budget Form (Section F.5).

Budget Justification: Include a budget justification for each year, for each Military Facility. A description of services or materials that are to be provided by the collaborating Military Facility is required. The Military Facility researcher(s) should coordinate with his/her local RM office (or equivalent) to prepare a sound budget and justification for the estimated costs. Applicant organizations must provide sufficient detail and justification to enable the Federal Government to determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort. In addition, the Military Facilities' direct and indirect costs to be supported when performing collaborative research with the extramural organization must meet the requirements of the DoD's Financial Management Regulation (FMR) 7000.14-R.

Direct Fund by Federal Agency: The DHA's Acquisitions Directorate (J-4) and Financial Operations (J-8) office will "direct fund" (via a Funding Authorization Document [FAD], Military Interdepartmental Purchase Request [MIPR], or other authorized method) the collaborating Military Facility to support all costs to be incurred in performance of the Military Facility's portion of the research project. When direct funded, these funds **will not** be included in the award amount to awardee.

C. Regulatory Requirements

A. Safety and Environmental Requirements

If the proposed research requires a safety and environmental compliance review, documents must be submitted upon request. Additional information is available at: <https://www.denix.osd.mil/>.

B. Research Protections Review Requirements

a. Use of Human Subjects, Human Anatomical Substances, Human Subject Data, and Human Cadavers.

- ***Investigators are not permitted to begin work on a protocol under the assumption that it is exempt from Institutional Review Board (IRB) review until a formal determination has been received.***

The Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)) Research Regulatory Oversight Office (R2O2) ensures that research conducted, supported, or otherwise subject to regulation by the DoD and involving human subjects, human anatomical substances, human subject data, and human cadavers are conducted in accordance with federal, DoD, DHA, and international regulatory requirements.

Investigators must protect the rights and welfare of individuals who participate as human subjects in research awarded pursuant to this FOA and must comply with the requirements of the Revised Common Rule at 45 CFR part 46; 32 CFR part 219; applicable provisions of DoD Instruction (DoDI) 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research (2011); and when applicable, the U.S. Food and Drug Administration (FDA) and other federal and state law and regulations.

Before commencing any research, or expending funding on such efforts, Investigators' local human research protection program (HRPP) policies and research protocols must be reviewed and approved by a DoD/DHA Human Research Protection Official (HRPO) to ensure that DoD/DHA regulations are met. Funds will not be released until the required approval has been obtained to ensure compliance with all requirements. HRPO reviews must be conducted using the electronic research management system, the Electronic IRB (EIRB, <https://eirb.csd.disa.mil>) using the checklist provided by R2O2.

This information should only be used as a guide; it is not intended to be a source for human subjects' protection regulations. Questions regarding applicable human subjects' protection regulations, policies, and guidance should be directed to the local IRB, the DHA HRPP, and/or the FDA, as appropriate.

The IRB is responsible for administrative review, approval, and oversight of research involving human subjects, human anatomical substances or data, and use of human cadavers. ***Research involving use of human subject data and/or specimens that is anticipated to be exempt from human subjects' protections regulations requires a determination from the PI's Institution as well as an HRPP determination from an Exemption Determination Official (EDO) or the HRPO.*** A timeframe for submission of the appropriate protocols and required approvals will be established during negotiations.

In addition to local IRB review and approval, Investigators must submit all DHA-funded research protocols involving human subjects for review and approval by the DoD/DHA HRPP before implementation of the research. The purpose of the HRPP review is not to duplicate the local IRB review, but rather to ensure the protocol complies with DoD/DHA regulatory and human subject protections requirements.

All DoD-conducted or -supported research, following local institutional review and approval, should be submitted to the DoD EIRB (<https://eirb.csd.disa.mil>). There are three types of review human subjects research can undergo:

- (1) **Requiring determination:** All proposed activities conducted by DoD personnel or supported by DoD for which there is uncertainty about whether they meet the definition of human subjects' research described above must be reviewed by an EDO for a determination prior to commencement of research activities.
 1. All proposed activities conducted by DoD personnel or supported by DoD for which the investigators are requesting an exemption from the requirements of 32 CFR 219.104 must be reviewed by an EDO for a determination.
 2. Proposed research that meets certain exemption categories will require both an exemption determination and a limited IRB review before the research activities can begin.
- (2) **Requiring Limited IRB Review:** Limited IRB reviews will be conducted in accordance with the requirements of 32 CFR 219.111.
- (3) **Requiring Full IRB Review:** All activities that meet the definition of research involving human subjects, are "non-exempt" as defined by DoDI 3216.02, and do not fall into one of the categories of exempt research must be reviewed and approved by an IRB before the research may begin. It is the PI's responsibility to submit an accurate and complete Protocol Application for review by the local IRB. When submitting for R2O2 review, submissions must be made using EIRB (<https://eirb.csd.disa.mil>). Submissions will not be accepted by any other means (e.g., paper, email).
 - Investigators must submit documentation of:
 - o Local IRB approval, as well as the IRB-approved research protocol, IRB-approved informed consent document, and other material they considered.
 - o Proof of completed human research training (e.g., training certificate or institutional verification of training for the PI and co-investigators, as appropriate).
 - o DoD Assurance. Each DoD institution engaged in non-exempt human subjects' research

- must either have its own or be covered under another institution's DoD Assurance. Investigators at institutions who do not have a DoD Assurance can enter into an Individual Investigator Agreement (IIA) with an institution that has a DoD Assurance. If required by the type of research being conducted, DoD institutions can also have a DHHS Office for Human Research Protection (OHRP) Federal Wide Assurance (FWA).
- o Claimed Exemptions. Any claimed exemption under 32 CFR 219.104, including the category of exemption, requires the supporting documentation considered by the PI's institution in making the determination (e.g., protocol, data collection tools, advertisements, etc.).
 - The documentation shall include a short rationale supporting the exemption determination.
 - Exemption Determination. Any determinations that the proposal does not contain activities that constitute research involving human subjects requires the inclusion of supporting documentation considered by the PI's institution in making the determination.

These requirements extend to both DoD-conducted research involving human subjects (i.e., intramural research) and research conducted by a non-DoD institution (i.e., extramural research). The research activities supported by DoD shall not begin until/unless the DoD HRPO concurs with the non-DoD IRB's risk determination and approval of the protocol. If the HRPO does not initially concur with the non-DoD IRB, the DoD-supported research activities shall not begin until after an agreement has been reached between the DoD HRPO and the non-DoD IRB. If the research is determined by the non-DoD IRB to be greater than minimal risk, the Investigators must also provide the name and contact information for the independent research monitor and a written summary of the monitors' duties, authorities, and responsibilities as approved by the IRB.

During the regulatory review process for research involving human subjects, the HRPP requirements must be addressed, and any changes to the already approved protocol must be approved as an amendment by the local IRB and DoD HRPO. The time to approval depends greatly on adherence to the requirements described within. Documents related to the use of human subjects or human anatomical substances will be requested if the proposal is recommended for funding. ***Allow at least 2 to 3 months for regulatory review and approval processes for studies involving human subjects.***

- ***IRBs must approve non-exempt research involving human subjects before any DoD-conducted or –supported activities involving human subjects may begin.***

For all collaborative research refer to 32 CFR 219.114, Corporative Research.

Modifications to an award, or research protocols, or the addition of subaward or subcontract will require HRPO review and approval. Research involving human subjects cannot continue until the awardee receives notification from the Grants Officer that the HRPO has approved the assurance as appropriate for the research under the award or modification, and that the HRPO has reviewed the

protocol and accepted the IRB approval or determination for compliance with federal, DoD, and DHA research protection requirements.

For research involving military personnel as subjects refer to DODI 3216.02, Enclosure 3, Section 7, Additional Protections for Human Subjects.

- *For additional assistance or clarification, please email DHA HRPP at dha.ncr.dha-cs-mgt.mbx.hrpp@mail.mil*

b. Clinical Trial Registry

PIs are required to register clinical trials individually on <https://clinicaltrials.gov/>. All trials that meet the definition of clinical trial on the NIH web page (<https://grants.nih.gov/policy/clinical-trials/definition.htm>) are required to register. Clinical trials must be registered before enrollment of the first patient. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per U.S. Public Law 110-85.

Research protocols that meet the definition of a clinical trial, as stated in 32 CFR 219.102(b), must post one IRB-approved informed consent, used to enroll subjects, on a publicly available federal website (such as clinicaltrials.gov) after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject in accordance with 32 CFR 219.116(h).

c. Biosafety and Biosecurity Requirements

Investigators must comply with applicable provisions of DoD Manual 6055.18-M, Safety Standards for Microbiological and Biomedical Laboratories, including ensuring compliance with standards meeting at least the minimum applicable requirements of the current edition of Centers for Disease Control and Prevention's, "Biosafety in Microbiological and Biomedical Laboratories (BMBL)," and National Institutes of Health's, "The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)." If a research protocol is determined to contain elements that require Institutional Biosafety Committee (IBC) or biosafety committee review, the IBC and/or biosafety committee must review the research and make a determination prior to the IRB review.

Investigators conducting research involving recombinant or synthetic nucleic acid molecules must comply with the NIH Guidelines. Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participants requires IBC, IRB, and Recombinant DNA Advisory Committee (RAC) review before research participant enrollment and commencement of research.

d. Use of Animals:

The DoD policies and requirements for the use of animals in DoD-supported research are described in DoDI 3216.01, Use of Animals in DoD Programs (2019). If animals are to be utilized in the research effort proposed, the Investigator must submit a Full or Abbreviated Appendix with supporting documentation (e.g., copies of Institutional Animal Care and Use Committee (IACUC) Approval, IACUC Approved Protocol, and most recent U.S. Department of Agriculture (USDA) Inspection Report) prior to award.

D. Reporting Requirements and Administrative Information

A. Reporting Requirements for Awards

The Government requires periodic reports to be submitted to continue the research and funding through the entire period of performance. Specific reports required by the Government will be described in each award and may include:

- Technical/Scientific:
These reports will present a detailed summary of scientific issues and accomplishments. A final report will be submitted within 30 days of the end of the performance period and will detail the findings, their potential impact to the military or Veteran population, and other issues for the entire project.
 - Monthly, quarterly, and/or annual progress reports
 - Final progress report
 - In-progress reviews
- Fiscal (SF 425 “Federal Financial Report”) (assistance agreements only):
 - Quarterly and/or annual reports
 - Final report
- Regulatory:
 - Research with Human Subjects – For DoD awards that include funding to support research with human subjects, the DoD/DHA HRPP requires submission of institutional continuing review reports and study event and modification reports. Questions related to HRPO review requirements should be directed to the DHA HRPP mailbox at dha.ncr.dha-cs-mgt.mbx.hrpp@mail.mil.

B. Disclosure of Proprietary Information

Do not include proprietary information in a pre-application or abstract. Proprietary information should only be included in a full proposal if necessary for evaluation.

Proprietary information submitted in a proposal may be disclosed outside the Government for the sole purpose of evaluation. Evaluators must agree that proprietary information in the proposal will be used for evaluation purposes only and will not be further disclosed or used. All proposal may be subject to public release under the FOIA.

Proposals for funded projects will be subject to public release under the FOIA to the extent that they are incorporated into an award document; proposals that are not selected for funding will not be subject to public release.

C. Marking of Proprietary Information

Conspicuously and legibly mark any proprietary information that is included in the proposal.

D. Award Notices

Awards are made to organizations, not to individual PIs. For this funding opportunity The Washington Headquarters, Acquisition Directorate (WHS/AD) will issue awards primarily through the award of assistance agreements (grants and cooperative agreements). The type of instrument used to reflect the business relationship between the organization and the Government will be determined by the Government before award.

An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a “thing of value,” to a “state, local government,” or “other recipient,” to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

Only a Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing document.

E. Inquiry Review

If application proposal is not recommended for funding, the organization or PI may submit an inquiry within 15 business days after the notification email is sent. Inquiries submitted after 15 business days will not be considered.

The inquiry must specifically address a factual or procedural error that is believed to have occurred during review of the proposal. Inquiries in response to funding recommendations should be submitted to the DoD Grants Officers can be contacted through.

F. Information Service

Applicants may use the technical reference facilities of Defense Technical Information Center (DTIC). DTIC or the National Technical Information Service (NTIS) to acquire information regarding existing research to avoid duplication of scientific and engineering effort. The DTIC physical address is 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218; the website is <http://www.dtic.mil>; and the telephone number is 800-225-3842. NTIS is located at 5285 Port Royal Road, Springfield, VA 22161; the website is www.ntis.gov; and the telephone number is 703-605-

6000.

G. Freedom of Information Act Requests

The FOIA (5 USC 552) provides a statutory basis for public access to official Government records. “Records” are defined to include documentation received by the Government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the Act (www.usdoj.gov/oip/index.html).

When an FOIA request asks for information contained in a successful proposal that has been incorporated into an award document, the submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by Office of the General Council in making its final determination concerning which information is or is not releasable. If information requested is releasable, the submitter will be given notice of DHA’s intent to release and will be provided a reasonable opportunity to assert available action.

H. Information Release, Acknowledgement, and Public Release

Acknowledgment: An awardee will be required to agree to the release of information pertaining to the research and development supported by the Federal agency. “Information” includes but is not limited to news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.

The following statements must be included in all information releases:

(1) All releases shall identify the award number and include a statement acknowledging the Federal sponsoring agency. The release shall also contain a statement that the opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the DoD. The requirement with specific language will be included in the award notice. Below is an example:

“This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency J9, Research and Development Directorate, through the (*insert program name*) under Award No. (XXXX). Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.”

(2) “In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture.” Include required assurances, approvals, documents and information specified on the ACURO website. (http://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro)

(3) “In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules.” (<http://www.nih.gov>)

(4) “In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.” (<http://www.cdc.gov/biosafety>)

Failure to include the above statements and adhere to the above regulations, when required, may result in loss of funding.

Publication of Findings: Publication of findings is a requirement of this submission. It is expected that at study completion researchers will submit their findings to an appropriate peer-reviewed journal for publication. Copies of all scientific publications, presentations, and reports resulting from this funding mechanism shall be submitted to DHA when published or completed even if beyond the period of performance to allow reporting to the DHP and Congress on the accomplishments of the program.

I. Contracted Fundamental Research

Any awards to universities or industry and funded by Basic Research funds (6.1), or to universities for on-campus research and funded by Applied Research funds (6.2), meet the DoD definition of “Contracted Fundamental Research.” The results of this research are to be unrestricted to the maximum extent possible. It is at US Government discretion to fund research with Budget Activity 3 or higher funds without placing restrictions on publication or personnel. The research shall not be considered fundamental in those rare and exceptional circumstances where the effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the award.

J. Sharing of Proposal Information

The DHA shares proposal information with other Federal funding agencies (e.g., NIH, National Science Foundation, Department of Veterans Affairs) to inform funding priorities and decisions, and to increase transparency. By sharing and leveraging this information, duplication of efforts can be avoided, allowing for the support of more investigators with Federal funds. The DHA believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health. Updates on DHA-funded awards including awardee information and published results are shared on DTIC. Additional information on DTIC can be found at http://www.dtic.mil/dtic/submit/security_classification.html

K. Sharing of Data and Research Resources

Data and research resources generated by funded research should be made available to the research community (which includes both scientific and consumer advocacy communities), and to the public. The expectations for sharing of data and research resources apply to all basic research, clinical studies, surveys, and other types of research funded by the FOA. This includes all data and research resources generated during the project’s period of performance as annotated in the assistance agreement:

- **Unique Data** are defined as data that cannot be readily replicated. Examples of unique data include large surveys that are expensive to replicate; studies of unique populations, such as patients to whom access is not widely available; studies conducted at unique times, such as during military conflict; studies of rare phenomena, such as rare diseases. (Adapted from http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique.)
- **Final Research Data** are defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. These are not

the summary statistics or tables; rather, final research data are the data on which summary statistics and tables are based. Final research data do not include laboratory notes or notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens. (Adapted from

http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique.)

- **Research Resources** include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, antibodies, reagents, animal models, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools, methods, laboratory equipment and machines. (Adapted from https://grants.nih.gov/grants/intell-property_64FR72090.pdf.)

Data and research resources generated from DHA-funded research should be made as widely available as possible while safeguarding the privacy of participants and protecting confidential and proprietary data and third-party intellectual property.

By sharing and leveraging data and research resources, duplication of efforts can be avoided, allowing for the support of more investigators with Federal funds. The DHA believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health. Depending on the research project, the PI may be required to participate in the following, which will be specified in the award:

- **Traumatic Brain Injury:** If the project includes traumatic brain injury (TBI) research, the PI may be required to make TBI data generated via an award available to the research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) Informatics System (<https://fitbir.nih.gov/content/policies-and-procedures>).
- **Clinical Trials:** If the project includes a clinical trial(s), the PI may be required to register the clinical trial(s) individually on the registry and database ClinicalTrials.gov (<https://www.clinicaltrials.gov/>).
- **Systems Biology:** If the project includes systems biology (SB)-related research, the PI may be required to make SB data, generated via an award, available to the research community by depositing research data into the SysBioCube system (<https://sysbiocube-abcc.ncifcrf.gov/>).

For additional information on DHA expectations and policies for data-sharing, refer to the Health.mil webpage: Submit a Data Sharing Application (<https://www.health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/Submit-a-Data-Sharing-Application>).

L. Property/Equipment

Unless otherwise specified in the award, the title to equipment or other tangible property acquired with Government funds will vest in institutions of higher education or with non-profit organizations whose primary purpose is conducting scientific research. Normally, the title will vest in the awardee if vesting will facilitate scientific research performed by the organization for the Government. Title to equipment or other tangible property acquired by for-profit organizations will conditionally vest in the organization subject to the requirements of 2 CFR 200. However, if the award is subsequently transferred to a new organization, the DoD reserves the right to require the transfer of equipment acquired with the award funds to the Federal Government or to an eligible third party.

M. Title to Inventions and Patents

In accordance with the Bayh-Dole Act (Title 35, U.S.C., Sections 200 et seq.), the recipient and collaborators may elect to retain title to their subject inventions and technical data, subject to meeting the reporting and patent filing requirements and retained rights to the Federal Government. The Federal Government shall, at a minimum, retain non-exclusive rights for the use of such inventions. Instructions in the assistance agreement concerning subject inventions must be followed. The FAR and DFARS govern the disposition of technical data rights, and generally the ownership of technical data is determined by the funding that governs it. For additional information, reference:

Assistance Agreements: 2 CFR 200.315-316

N. PI Changes and Award Transfers

Transfer of an Assistance Agreement to New Organization: Unless restricted by the specific FOA, a change in organizational affiliation will be considered on a case-by-case basis by the DoD Contacting/Grants Officer. If approved, the PI's original organization will be required to agree to relinquish the award. The new organization will be required to resubmit the entire proposal on behalf of the PI, including regulatory documentation. Extended times for transfer may put the award funding at risk. A transfer will not, unless under extraordinary circumstances, be allowed for any organization that includes a study site/clinical trial at its location.

Change in PI: Unless otherwise restricted, changes in PI will be allowed at the discretion of the DoD Grants Officer, provided that the intent of the award mechanism is met.

E. National Policy Requirements

The National Policy Requirements are available in full text at <https://www.federalregister.gov/documents/2016/11/07/2016-25700/national-policy-requirements-general-award-terms-and-conditions>.

A. Certification

Certification of compliance with the national policy requirement regarding lobbying activities is required from all recipients of awards over \$100,000. Submission of this certification is required by 31 USC 1352 and is a prerequisite for making or entering into an award over \$100,000. Complete SFLLL (Disclosure of Lobbying Activities), if applicable, and attach to Block 18 of SF424 (R&R) (Application for Federal Assistance) Form.

Certification for Contracts, Grants, Loans, and Cooperative Agreements

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

- (1) No Federally appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, and the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.
- (2) If any funds other than Federal appropriated funds have been paid or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit SFLLL (Disclosure of Lobbying Activities), in accordance with its instructions.
- (3) The undersigned shall require that the language of this certification be included in the award documents for all sub-awards at all tiers (including sub-grants, and contracts under grants, loans, and cooperative agreements) and that all sub-recipients shall certify and disclose accordingly.

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

B. Representations

All applicants are required to complete the representations below and submit with each proposal. Upload a document into Grants.gov under Attachments.

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

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

- (1) Is _____ is not _____ a Corporation (“Corporation” means any entity, including any institution of higher education, other nonprofit organization, or for-profit entity that has filed articles of incorporation). If the organization IS a corporation, complete (2) and (3) below.
- (2) Is _____ is not _____ a Corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.
- (3) Is _____ is not _____ a Corporation that was convicted of a criminal violation under any Federal law within the preceding 24 months.

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

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

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

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

Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

National Policy Requirements

The awardee must comply with the following requirements, as applicable. Awards will incorporate the most recent set of National Policy Requirements available at the time of award.

- Nondiscrimination
- Environmental Standards
- Live Organisms (Human Subjects and Animals)
- Debarment and Suspension
- Drug-Free Workplace
- Lobbying
- Officials Not to Benefit
- Hatch Act
- Native American Graves Protection and Repatriation Act
- Fly America Act
- Use of United States Flag Vessels
- Research Misconduct
- Requirements for an Institution of Higher Education Concerning Military Recruiters and Reserve Officer Training Corps
- Historic Preservation
- Relocation and Real Property Acquisition
- Confidentiality of Patient Records
- Pro-Children Act
- Constitution Day
- Trafficking in Persons
- Whistleblower Protections
- Certain Internal Confidentiality Agreements

C. Grant and Cooperative Agreement Proposals:

1) Grant awards greater than \$100,000 require a certification of compliance with a national policy mandate concerning lobbying. Statutes and Government-wide regulations require the certification to be submitted before award. When submitting your grant through Grants.gov, by completing blocks 18 and 19 of the SF 424 (R&R) Form, the grant applicant is providing the certification on lobbying required by 32 CFR Part 28; otherwise a copy signed by the AOR must be provided. Below is the required certification:

CERTIFICATION AT APPENDIX A TO 32 CFR PART 28 REGARDING LOBBYING:
Certification for Contracts, Grants, Loans, and Cooperative Agreements the undersigned certifies, to the best of his or her knowledge and belief, that:

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

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

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

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

- (2) In accordance with Continuing Appropriations Act, 2017 (Pub. L. 114-223), or any other Act that extends to fiscal year (FY) 2017 funds the same prohibitions as contained in section 743, division E, title VII, of the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), none of the funds appropriated or otherwise made available by that or any other Act may be made available for a grant or cooperative agreement with an entity that requires its employees or contractors seeking to report fraud, waste, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting those employees or contractors from lawfully reporting that waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive the information.

PROHIBITION ON CONTRACTING WITH ENTITIES THAT REQUIRED CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS – REPRESENTATION

Agreement with the representation below will be affirmed by checking the "I agree" box in block 17 of the SF424 (R&R) as part of the electronic proposal submitted via Grants.gov. The representation reads as follows:

By submission of its proposal, the applicant represents that it does not require any of its employees, contractors, or sub-recipients seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting those employees, contractors, sub-recipients from lawfully reporting that waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

*Note that: Section 743 states that it does not contravene requirements applicable to SF 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

- (3) Recipients are required to submit the following representation with the application package following the instructions at Section II.D.2.f.ii of this FOA:

REPRESENTATIONS UNDER DOD ASSISTANCE AGREEMENTS: APPROPRIATIONS PROVISIONS ON TAX DELINQUENCY AND FELONY CONVICTIONS

The applicant is () is not () a “Corporation” meaning any entity, including any institution of higher education, other nonprofit organization, or for-profit entity that has filed articles of incorporation.

If the applicant is a “Corporation” please complete the following representations:

- (a) The applicant represents that it is () is not () a corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.
- (b) The applicant represents that it is () is not () is not a corporation that was convicted of a criminal violation under any Federal law within the preceding 24 months.

NOTE: If an applicant responds in the affirmative to either of the above representations, the applicant is ineligible to receive an award unless the agency suspension and debarment official (SDO) has considered suspension or debarment and determined that further action is not required to protect the Government’s interests. The applicant therefore should provide information about its tax liability or conviction to the agency’s SDO as soon as it can do so, to facilitate completion of the required considerations before award decisions are made.

Assistance Instruments and Contracts: Awards may be subject to biological safety program requirements.

DRUG-FREE WORKPLACE:

- (1) Assistance Instruments: The recipient must comply with drug-free workplace requirements in Subpart B of 2 CFR part 26, which is the DoD implementation of 41 U.S.C. chapter 81, “Drug-Free Workplace.”
- (2) Contracts: The appropriate clause(s) shall be added to the award.

DEBARMENT AND SUSPENSION:

- (1) Assistance Instruments: The recipient must comply with requirements regarding debarment and suspension in Subpart C of 2 CFR part 180, as adopted by DoD at 2 CFR part 1125. This includes requirements concerning the recipient’s principals under an award, as well as requirements concerning the recipient’s procurement transactions and sub-awards that are implemented in DoD Research and Development General Terms and Conditions PROC Articles

I through III and SUB Article II.

(2) Contracts: The appropriate clause(s) shall be added to the award.

APPENDIX 2

Grants.gov Application Submission and Receipt Procedures

This section provides the application submission and receipt instructions for Washington Headquarters Services, Acquisition Directorate (WHS/AD) on behalf of Defense Health Agency (DHA J-9) program applications. Please read the following instructions carefully and completely.

1. Electronic Delivery

WHS/AD on behalf of DHA J-9 is participating in the Grants.gov initiative to provide the grant community with a single site to find and apply for grant funding opportunities. WHS/AD encourages applicants to submit their applications online through Grants.gov.

2. How to Register to Apply through Grants.gov

a. *Instructions:* Read the instructions below about registering to apply for DHA J-9 funds. Applicants should read the registration instructions carefully and prepare the information requested before beginning the registration process. Reviewing and assembling the required information before beginning the registration process will alleviate last-minute searches for required information.

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

Creating a Grants.gov account can be completed online in minutes, but DUNS and SAM registrations may take several weeks. Therefore, an organization's registration should be done in sufficient time to ensure it does not impact the entity's ability to meet required application submission deadlines.

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

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

1) *Obtain a DUNS Number:* All entities applying for funding, including renewal funding, must have a DUNS Number from Dun & Bradstreet (D&B). Applicants must enter the DUNS Number in the data entry field labeled "Organizational DUNS" on the SF-424 form. For more detailed instructions for obtaining a DUNS Number, refer to:

<https://www.grants.gov/web/grants/applicants/organization-registration/step-1-obtain-duns-number.html>

2) *Register with SAM:* All organizations applying online through Grants.gov must register with the System for Award Management (SAM). Failure to register with SAM will prevent your organization from applying through Grants.gov. SAM registration must be renewed annually. For more detailed instructions for registering with SAM, refer to:

<https://www.grants.gov/web/grants/applicants/organization-registration/step-2-register-with-sam.html>

3) *Create a Grants.gov Account:* The next step is to register an account with Grants.gov. Follow the on-screen instructions or refer to the detailed instructions here:

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

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

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

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

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

3. How to Submit an Application to WHS/AD via Grants.gov

Grants.gov applicants can apply online using Workspace. Workspace is a shared, online environment where members of a grant team may simultaneously access and edit different webforms within an application. For each funding opportunity announcement (FOA), you can create individual instances of a workspace.

Below is an overview of applying on Grants.gov. For access to complete instructions on how to apply for opportunities, refer to:

<https://www.grants.gov/web/grants/applicants/workspace-overview.html>

1) *Create a Workspace*: Creating a workspace allows you to complete it online and route it through your organization for review before submitting.

2) *Complete a Workspace*: Add participants to the workspace to work on the application together, complete all the required forms online or by downloading PDF versions, and check for errors before submission. The Workspace progress bar will display the state of your application process as you apply. As you apply using Workspace, you may click the blue question mark icon near the upper-right corner of each page to access context-sensitive help.

a. *Adobe Reader*: If you decide not to apply by filling out webforms you can download individual PDF forms in Workspace. The individual PDF forms can be downloaded and saved to your local device storage, network drive(s), or external drives, then accessed through Adobe Reader.

NOTE: Visit the Adobe Software Compatibility page on Grants.gov to download the appropriate version of the software at: <https://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html>

b. *Mandatory Fields in Forms:* In the forms, you will note fields marked with an asterisk and a different background color. These fields are mandatory fields that must be completed to successfully submit your application.

c. *Complete SF-424 Fields First:* The forms are designed to fill in common required fields across other forms, such as the applicant name, address, and DUNS Number. Once it is completed, the information will transfer to the other forms.

3) *Submit a Workspace:* An application may be submitted through workspace by clicking the Sign and Submit button on the Manage Workspace page, under the Forms tab. Grants.gov recommends submitting your application package at least 24-48 hours prior to the close date to provide you with time to correct any potential technical issues that may disrupt the application submission.

4) *Track a Workspace Submission:* After successfully submitting a workspace application, a Grants.gov Tracking Number (GRANTXXXXXXX) is automatically assigned to the application. The number will be listed on the Confirmation page that is generated after submission. Using the tracking number, access the Track My Application page under the Applicants tab or the Details tab in the submitted workspace.

For additional training resources, including video tutorials, refer to:
<https://www.grants.gov/web/grants/applicants/applicant-training.html>

Applicant Support: Grants.gov provides applicants 24/7 support via the toll-free number 1-800-518-4726 and email at support@grants.gov. For questions related to the specific grant opportunity, contact the number listed in the application package of the grant you are applying for.

If you are experiencing difficulties with your submission, it is best to call the Grants.gov Support Center and get a ticket number. The Support Center ticket number will assist WHS/AD with tracking your issue and understanding background information on the issue.

4. Timely Receipt Requirements and Proof of Timely Submission

a. *Online Submission.* All applications must be received by 23 August 2019 Eastern time on the due date established for each program. Proof of timely submission is automatically recorded by Grants.gov. An electronic date/time stamp is generated within the system when the application is successfully received by Grants.gov. The applicant with the AOR role who submitted the application will receive an acknowledgement of receipt and a tracking number (GRANTXXXXXXX) from Grants.gov with the successful transmission of their application. This applicant with the AOR role will also receive the official date/time stamp and Grants.gov Tracking number in an email serving as proof of their timely submission.

When WHS/AD successfully retrieves the application from Grants.gov, and acknowledges the download of submissions, Grants.gov will provide an electronic acknowledgment of receipt of the application to the email address of the applicant with the AOR role who submitted the application. Again, proof of timely submission shall be the official date and time that Grants.gov receives your application. Applications received by Grants.gov after the established due date for the program will be considered late and will not be considered for funding by DHA J9.

Applicants using slow internet, such as dial-up connections, should be aware that transmission can take some time before Grants.gov receives your application. Again, Grants.gov will provide either an error or a successfully received transmission in the form of an email sent to the applicant with the AOR role attempting to submit the application. The Grants.gov Support Center reports that some applicants end the transmission because they think that nothing is occurring during the transmission process. Please be patient and give the system time to process the application.

APPENDIX 3

STATEMENT OF SUBSTANTIAL INVOLVEMENT

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

RECIPIENT’S 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 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 Program Manager and incorporating DHA comments.

Presenting the project results at appropriate technical conferences or meetings as directed by the DHA Program Manager.

Provide all knowledge products and results.

DHA RESPONSIBILITIES. DHA is responsible for:

Reviewing project plans, in a timely manner, and recommending alternate approaches to the work effort if the plans do not address critical HSR 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 HSR socialization, including disseminating program results through presentations and publications.

Serving as a scientific/technical liaison between awardees and other program or industry staff.