# I. OVERVIEW OF THE FUNDING OPPORTUNITY

**Program Announcement for the Department of Defense** 

**Defense Health Program** 

**Congressionally Directed Medical Research Programs** 

# **Arthritis Research Program**

# **Focused Research Award**

**Announcement Type: Initial** 

Funding Opportunity Number: HT942524ATRPFRA

Assistance Listing Number: 12.420 Military Medical Research and Development

### SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), October 16, 2024
- Application Submission Deadline: 11:59 p.m. ET, October 30, 2024
- End of Application Verification Period: 5:00 p.m. ET, November 4, 2024
- Peer Review: January 2025
- **Programmatic Review:** March 2025

This program announcement must be read in conjunction with the General Application Instructions, version 901. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

# **TABLE OF CONTENTS**

I.	OVERVIEW OF THE FUNDING OPPORTUNITY	1
Π.	DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY	3
	II.A. Program Description	3
	II.A.1. FY24 ATRP Focused Research Award Focus Areas	4
	II.A.2. Award History	4
	II.B. Award Information	4
	II.C. Eligibility Information	7
	II.C.1. Eligible Applicants	7
	II.C.2. Cost Sharing	7
	II.C.3. Other	7
	II.D. Application and Submission Information.	8
	II.D.1. Location of Application Package	8
	II.D.2. Content and Form of the Application Submission	9
	II.D.2.a. Step 1: Pre-Application Submission	9
	II.D.2.b. Step 2: Full Application Submission	10
	II.D.2.c. Applicant Verification of Full Application Submission in eBRAP	18
	II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)	18
	II.D.4. Submission Dates and Times	18
	II.D.5. Funding Restrictions	19
	II.D.6. Other Submission Requirements	19
	II.E. Application Review Information	20
	II.E.1. Criteria	20
	II.E.2. Application Review and Selection Process	22
	II.E.3. Integrity and Performance Information	22
	II.F. Federal Award Administration Information	23
	II.F.1. Federal Award Notices	23
	II.F.2. PI Changes and Award Transfers	24
	II.F.3. Administrative and National Policy Requirements	24
	II.F.4. Reporting	
	II.G. Federal Awarding Agency Contacts	25
	II.G.1. eBRAP Help Desk	
	II.G.2. Grants.gov Contact Center	
	II.H. Other Information	
	II.H.1. Program Announcement and General Application Instructions Versions	
	II.H.2. Administrative Actions	
	II.H.3. Full Application Submission Checklist	
ΑF	PPENDIX 1: ACRONYM LIST	29

# II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

# **II.A. Program Description**

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Arthritis Research Program (ATRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the ATRP in FY24 to provide support for research of high potential impact and exceptional scientific merit focused on reducing the detrimental impact of arthritis on Service Members and their retention. Funding for the ATRP will be used to support research on all forms of arthritis. The total appropriation for the ATRP for FY24 is \$10 million (M).

In May 2024, the ATRP held a stakeholders meeting to engage arthritis research scientists, clinicians, and military experts, as well as lived-experience subject matter experts/consumers, in an open-dialogue forum to (1) identify knowledge and capability gaps to help inform future investment discussions, (2) identify the most impactful areas within the research continuum for additional arthritis research, and (3) acknowledge barriers to the implementation of interventions to reduce the burden of arthritis, particularly as they relate to the detrimental impact of arthritis on Service Members and their retention. Outcomes from the stakeholders meeting were considered by the ATRP Programmatic Panel in developing the FY24 program investment strategy. A summary of the FY24 ATRP stakeholders meeting, and the stakeholder-identified research gaps, are available at <a href="https://cdmrp.health.mil/atrp/default">https://cdmrp.health.mil/atrp/default</a>.

The vision of the ATRP is to lessen the burden of, and ultimately cure, arthritis.

The mission of the ATRP is to fund high-impact research to optimize the health and well-being of all people affected by arthritis and improve Service Member readiness and retention.

The FY24 ATRP challenges the scientific community to address the most significant gaps in the care and well-being of Service Members and all persons impacted by arthritis. The program is particularly interested in reducing the burden of arthritis in Service Members and its impact to their readiness and retention. It is expected that research findings from awards funded by the ATRP will also benefit those that receive care through the Military Health System, and those within the general population. As mandated by Congress, the ATRP will support high-impact research on any types of arthritis, including but not limited to osteoarthritis, post-traumatic arthritis, inflammatory arthritis, juvenile arthritis, and rheumatoid arthritis. The ATRP encourages applications that examine the impact of and provide solutions for arthritis in understudied populations such as women, minorities, or less prevalent arthritis types.

Applications from investigators within the military services and applications involving multiinstitutional and multidisciplinary collaborations among academia, industry, the military services, the U.S. Department of Veterans Affairs (VA), and other federal government agencies are encouraged.

### II.A.1. FY24 ATRP Focused Research Award Focus Areas

To meet the intent of the funding opportunity, applications submitted to this program announcement must address one of the following FY24 ATRP Focused Research Award (FRA) focus areas listed below.

Selection of the appropriate focus area is the responsibility of the applicant.

### • Prevention:

o Identify technologies, solutions, or knowledge products for the preventative management of arthritis, especially for post-traumatic osteoarthritis.

# • Diagnosis and Progression Mitigation:

 Identify factors capable of predicting the onset or progression of disease, especially in understudied populations.

# • Intervention/Treatment:

 Develop conceptually novel or innovative solutions that address the multifactorial burden of arthritis. This may include solutions which address one or more of the following factors: pain or other symptoms, function, psychosocial factors, comorbidities, or the pathologic burden of disease.

# **II.A.2.** Award History

The ATRP Focused Research Award mechanism is being offered for the first time in FY24.

# **II.B.** Award Information

The FY24 ATRP FRA is intended to support conceptually innovative, high-risk/potentially high-reward research that could ultimately lead to critical discoveries and/or improvements in patient care or quality of life for people impacted by arthritis. Research addressing **all types of arthritis** is encouraged including but not limited to osteoarthritis, post-traumatic arthritis, inflammatory arthritis, juvenile arthritis, and rheumatoid arthritis. The ATRP encourages applications that address sex as a biological variable and understudied arthritis types. The ATRP also encourages applicants to consider whether large data sets or existing studies/consortia can be leveraged to maximize the potential impact of proposed studies.

Applicants must address how the proposed research may eventually impact patient care and reduce the burden of disease. It is expected that any research findings would benefit Service Members, their Families, Veterans, and the general public. To meet the intent of the award mechanism, applications must specifically address at least one FY24 ATRP FRA focus area, listed in Section II.A.1, above.

Important aspects of this award mechanism include:

**Impact:** A key aspect of this award mechanism is impact. The application should explicitly state how outcomes of the proposed research will have a significant impact on the advancement of arthritis research, potential for exploration of novel ideas, and/or patient care practices. The application should clearly indicate how the research addresses the impact of arthritis in the military, which may include its effect on Service Member recruitment, retention, and recovery. Applicants may also choose to include impacts to the Military Health System, which provides health care support to Service Members and their Families (Eligibility | TRICARE).

**Research Levels:** The FY24 ATRP FRA offers funding for two Research Levels (refer to Section II.D.5 Funding Restrictions). *Only one Research Level category may be chosen per application*. It is the responsibility of the applicant to select the level that aligns with the scope of the proposed research. The Research Level should be selected based on the research scope and not on the amount of the budget. The following are generalized descriptions of the scope of the research appropriate for each level:

- Research Level 1: Supports exploratory, high-risk/high-reward research that is in the early stages of idea development. Research must have the potential to yield new avenues of investigation, such as new approaches, new research tools, or new paradigms. Early career investigators are particularly encouraged to apply to this research level.
- **Research Level 2:** Supports the advancement of preclinical research toward clinical translation.

**Preliminary data are required:** Applications must include preliminary and/or published data to support the proposed research project. **The included data may originate from other researchers or research conducted by the applicant(s).** Applicants must demonstrate logical reasoning for the proposed work. To be competitive, the application must include a sound scientific rationale and a well-formulated, testable hypothesis established through a critical review and analysis of the literature.

Advancing Women's Health Research and Innovation: The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health. The ATRP therefore encourages research that addresses how arthritis and arthritis care may affect women uniquely, disproportionately, or differently from men.

**Rigor of Experimental Design:** All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (<a href="https://www.nature.com/nature/journal/v490/n7419/full/nature11556.html">https://www.nature.com/nature/journal/v490/n7419/full/nature11556.html</a>). While these standards are written for preclinical studies, the basic principles of randomization, blinding,

sample-size estimation, and data handling derive from well-established best practices in clinical studies.

The FY24 ATRP FRA mechanism is intended to support preclinical or animal research and may not be used for clinical research or clinical trials. Applicants seeking funding for a clinical trial or clinical research should consider the FY24 ATRP Clinical Research Award mechanism (Funding Opportunity Number: HT9425FY24ATRPCRA).

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

- (1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or coinvestigator) does *not* seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.
- (2) Epidemiologic and behavioral studies that do *not* seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.
- (3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

The anticipated total costs budgeted for the entire period of performance for an FY24 ATRP FRA should not exceed \$500,000 (Research Level 1) or \$750,000 (Research Level 2). Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately \$2.5M to fund approximately two FRA – Research Level 1 applications and two FRA – Research Level 2 applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

# **II.C.** Eligibility Information

# **II.C.1.** Eligible Applicants

**II.C.1.a. Organization:** Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

**Extramural Organization:** An eligible non-Department of Defense (DOD) organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

**Intramural DOD Organization:** Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible *organizations*, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

# **II.C.1.b.** Principal Investigator

Independent investigators at all academic levels (or equivalent) may be named by the organization as the Principal Investigator (PI) on the application.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by or affiliated with an eligible organization.

# **II.C.2.** Cost Sharing

Cost sharing/matching is not an eligibility requirement.

### II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

Refer to <u>Section II.H.2</u>, <u>Administrative Actions</u>, for a list of administrative actions that may be taken if a pre-application or full application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

# **II.D. Application and Submission Information**

# **II.D.1.** Location of Application Package

Submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a *full application* (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

**eBRAP** (<a href="https://ebrap.org">https://ebrap.org</a>) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

**Grants.gov** (<a href="https://grants.gov">https://grants.gov</a>) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

# Step1: Submit Pre-Application (Extramural and Intramural Submissions) Letter of Intent Submitted Through eBRAP Step 2: Submit Full Application Submitted Through Grants.gov Intramural Submission Submitted Through eBRAP Verify Application Content in eBRAP

Application Submission Workflow

**Extramural Submission:** An application submitted by an <u>extramural organization</u> for an extramural or intramural PI working within an extramural or intramural organization. For

example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524ATRPFRA from Grants.gov (<a href="https://grants.gov">https://grants.gov</a>). Full applications from extramural organizations *must* be submitted through Grants.gov.

**Intramural Submission:** An application submitted by an <u>intramural DOD organization</u> for an investigator employed by that organization. Intramural DOD organizations <u>may</u> submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524ATRPFRA from the anticipated submission portal eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

# **II.D.2.** Content and Form of the Application Submission

Submitting applications that propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

Unnecessary duplication of funding, or accepting funding from more than one source for the same research, is prohibited. See CDMRP's full position on research duplication at <a href="https://cdmrp.health.mil/funding/researchDup">https://cdmrp.health.mil/funding/researchDup</a>.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 ATRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

# **II.D.2.a.** Step 1: Pre-Application Submission

Regardless of submission type (i.e., extramural or intramural), all pre-application components must be submitted by the PI through eBRAP.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-

application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at <a href="help@eBRAP.org">help@eBRAP.org</a> or 301-682-5507 prior to the application submission deadline.

When starting the pre-application, applicants will be asked to select a "Mechanism Option". Please be sure to select the correct option appropriate to your intended application:

Application Includes:	<b>Select Option:</b>
Focused Research Award – Research Level 1	FRA-RL1
Focused Research Award – Research Level 2	FRA-RL2

# **II.D.2.a.i.** Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for detailed instructions regarding pre-application submission):

• Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the focus area under which the application will be submitted.

LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.

# II.D.2.b. Step 2: Full Application Submission

# II.D.2.b.i. Full Application Submission Type

**Extramural Submissions:** Full applications from extramural organizations *must* be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

**Intramural Submissions:** Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

# **II.D.2.b.ii.** Full Application Submission Components

Each application submission must include the completed full application package for this program announcement. See <u>Section II.H.3</u> of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form (Extramural Submissions Only): Refer to the General Application Instructions, Section IV.B, for detailed information.

# (b) Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 2.

Attachment 1: Project Narrative (page limit varies by research level; see below for 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) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

# **Page Limit:**

- **Research Level 1:** 6-page limit

- **Research Level 2:** 10-page limit

Describe the proposed project in detail using the outline below.

- Background/Rationale: The background section should detail the scientific rationale for the study, establish the study's relevance, and clearly explain the basis for the study questions and/or study hypotheses.
  - Research Level 1: Describe the idea that the proposed research will explore and develop, clearly stating the objective(s) to be reached and/or hypothesis(es) to be tested. Preliminary or published data, originating from research conducted by the applicant(s) or by other researchers, to support the hypothesis(es) are required.
  - Research Level 2: Describe the proof-of-concept finding(s) that the proposed research aims to move forward to the next phase of development, clearly stating the objective(s) to be reached and/or the hypothesis(es) to be tested. Present sufficient preliminary data to support the readiness of the objective(s), the soundness of the hypothesis(es), and the feasibility of the approach(es).

- Specific Aims: Concisely describe the project's aims. Describe how the study design supports the accomplishment of the aims.
- Research Strategy: Describe the experimental design, methods, and analyses, including controls, in sufficient detail so that the appropriateness and feasibility of the research strategy, including whether the proposed work can be completed within the proposed period of performance, can be fully evaluated.
  - If cell lines or animals are to be used, justify the selection of the proposed cell line(s) or animal model(s), and availability of and access to the model(s) proposed. Briefly describe the key elements of the study/studies as they relate to the overall project. If animal studies are proposed, detailed information is required in Attachment 7, Animal Research Plan.
  - If the proposed research involves access to DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to the General Application Instructions, Appendix 4, for additional considerations.
  - Address potential problems that may arise and present alternative methods and approaches to mitigate or resolve the problems.
  - Describe the statistical plan and the rationale for the statistical methodology.
  - Research Level 2 applications must also:
    - Provide a sample size estimate and the method by which it was derived, including power analysis calculation, if applicable.
    - Describe measures to be taken to reduce bias and achieve reproducible and rigorous results, including controls, blinding, randomization, and data handling, as applicable.
- Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf". Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support (two-page limit per letter is recommended): 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. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable; two-page limit per letter is recommended): Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.
- Intellectual Property: Information can be found in the 2 CFR 200.315, "Intangible Property."
  - Intellectual and Material Property Plan (*if applicable*): Provide a plan for resolving intellectual and material property issues among participating organizations.
  - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instructions

- <u>3200.12</u>. *Do not duplicate the Data and Research Resources Sharing Plan.* Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.
- Data and Research Resources Sharing Plan: Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page <a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a> for more information about CDMRP's expectations for making data and research resources publicly available.
- Use of DOD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to DOD resources or databases.
  - Use of VA Resources (*if applicable*): Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf". The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

Background: Present the ideas and scientific rationale behind the proposed research project. Clearly indicate whether the proposed project is exploring new ideas or is advancing more mature preclinical research toward clinical translation. Describe how the proposed research aligns with the selected FY24 ATRP focus area.

- **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Describe the study design, including appropriate controls.
- Impact: Briefly summarize the potential impact of the proposed research on the health and well-being of persons impacted by arthritis and its relevance to the military.
- Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf". The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. Abstracts of all funded research projects will be posted publicly. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Do not duplicate the technical abstract.

Lay abstracts should address the points outlined below *in a manner that will be readily understood by readers without a background in science or medicine*. Avoid overuse of scientific jargon, acronyms, and abbreviations.

- Summarize the objectives and rationale for the proposed research.
- What population will the research help, and how will it help them?
- What are the potential applications, benefits, and risks of the anticipated outcomes?
- What are the likely contributions of the proposed research project to advancing research, patient care, and/or quality of life? How might it impact Service Members and the military?
- Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf". Refer to the eBRAP "Funding Opportunities & Forms" web page
   (<a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>) for the suggested SOW format and recommended strategies for assembling the SOW.
  - For the Focused Research Award refer to the "Example: Assembling a Generic Statement of Work" for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.
- Attachment 6: Impact and Relevance to Military Health Statement (one-page limit): Upload as "Impact.pdf". The Impact and Relevance to Military Health Statement should be written with a broad audience in mind, including readers without a background in science or medicine.

- Describe the anticipated short- and long-term impact of the proposed work on the advancement of arthritis research, potential for exploration of novel ideas, and/or patient care practices, particularly as it relates to the selected FY24 ATRP focus area.
- Demonstrate how the proposed research project is relevant to military health and/or the health care needs and quality of life of Service Members, Veterans, or military Family member population(s) impacted by arthritis.
- Explicitly state how outcomes of the proposed research may ultimately be applied to lessen the impact of arthritis in the military, which may include its effect on Service Member recruitment, retention, and recovery.
- Attachment 7: Animal Research Plan (five-page limit): Upload as
   "AnimalResPlan.pdf". (Attachment 7 is only applicable and required for applications proposing animal studies.)

If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at <a href="https://arriveguidelines.org/arrive-guidelines">https://arriveguidelines.org/arrive-guidelines</a>. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why
  the animal species, strain, and model(s) being used can address the scientific
  objectives and, where appropriate, the study's relevance to human biology.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- Attachment 8: Representations (Extramural Submissions Only): Upload as
   "RequiredReps.pdf". All extramural applicants must complete and submit the Required Representations template available on eBRAP (<a href="https://ebrap.org/eBRAP/">https://ebrap.org/eBRAP/</a>

- <u>public/Program.htm</u>). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
- Attachment 9: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as "IGBudget.pdf". If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The total costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.
- (c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.
- (d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.
  - o PI Biographical Sketch (six-page limit): Upload as "Biosketch LastName.pdf".
  - PI Previous/Current/Pending Support (no page limit): Upload as "Support LastName.pdf".
  - **Key Personnel Biographical Sketches (six-page limit each):** Upload as "Biosketch\_LastName.pdf".
  - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support\_LastName.pdf".
- (e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.
  - Budget Justification (no page limit): For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.
- (f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

- (g) Research & Related Subaward Budget Attachment(s) Form (*if applicable, Extramural Submissions Only*): Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.
  - o **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
  - Intramural DOD Subaward: Complete a separate "<u>Suggested</u>
     <u>Intragovernmental/Intramural Budget Form</u>" for each intramural DOD subaward and
     upload as a single document titled **IGBudget.pdf** to Grants.gov as <u>Attachment 9</u>.

# II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the full application submission deadline. Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

# II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (<a href="https://www.sam.gov/content/home">https://www.sam.gov/content/home</a>) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

### **II.D.4.** Submission Dates and Times

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity.

# **II.D.5.** Funding Restrictions

# **Research Level 1:**

The maximum period of performance is 2 years.

The application's total costs budgeted for the entire period of performance should not exceed \$500,000. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the 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.

# **Research Level 2:**

The maximum period of performance is 3 years.

The application's total costs budgeted for the entire period of performance should not exceed \$750,000. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the 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 3 years.

For this award mechanism (both Research Levels), direct costs:

May be requested for (not all-inclusive):

• Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the ATRP FRA.

Must not be requested for:

- Clinical trial costs
- Clinical research costs

# **II.D.6.** Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

# **II.E. Application Review Information**

# II.E.1. Criteria

# II.E.1.a. Peer Review

To determine technical merit, all applications will be individually evaluated according to the following **scored criteria**, which are listed in decreasing order of importance:

# • Impact

- o How well the proposed study addresses the selected FY24 ATRP FRA focus area.
- To what extent the proposed research will advance arthritis research, exploration of novel ideas, and/or patient care practices.
- Research Level 1 only: If successful, to what extent the proposed work will explore and develop new research ideas in arthritis.
- Research Level 2 only: If successful, to what extent the proposed research will lead to significant advancement toward clinical translation.

# • Research Strategy

- How well the scientific rationale supports the project, as demonstrated by logical reasoning and the presentation of preliminary data and/or published data.
- How well the hypotheses or objectives, aims, experimental design, data management plan (if applicable), methods, and analyses are developed and support successful completion of the project aims.
- To what degree the data and research resources sharing plan is appropriate for the proposed study.
- If applicable, how well the animal study (or studies) is designed to achieve the objectives, including the choice and availability of model and endpoints/outcome measures to be used.
- Research Level 2 only: How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling, as appropriate.
- Research Level 2 only: To what degree the statistical plan and power analysis are appropriate for the proposed project and future transition to the next level of development.

# Feasibility

- o To what extent the experimental design, methods, and analyses, including controls, are feasible.
- How well the application acknowledges potential problems and addresses alternative methods.
- Whether the research can be completed within the proposed period of performance.

# Personnel

- Whether the levels of effort by the PI and key personnel are appropriate for the successful conduct of the proposed work.
- Research Level 1 only: Whether the PI has the training required to complete at least one key aspect of the proposed research, as evidenced by coursework/degree or research experience.
- Research Level 2 only: To what extent the backgrounds, expertise, experience, and past
  accomplishments of the PI and key personnel are appropriate to accomplish the proposed
  research project.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

# Budget

• Whether the budget is appropriate for the proposed research.

# Environment

- To what extent the scientific environment is appropriate for the proposed research project.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources.
- To what extent the quality and level of institutional support are appropriate for the proposed research project.

# • Application Presentation

To what extent the writing, clarity, and presentation of the application components influence the review.

# **II.E.1.b.** Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the Defense Health Program and FY24 ATRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio balance
  - Relative impact and relevance to military health

# **II.E.2.** Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in <u>Section II.E.1.b</u>, <u>Programmatic Review</u>. Additional information about the two-tier process used by the CDMRP can be found at <a href="https://cdmrp.health.mil/about/2tierRevProcess">https://cdmrp.health.mil/about/2tierRevProcess</a>.* 

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

# **II.E.3.** Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the

federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

# II.F. Federal Award Administration Information

### **II.F.1. Federal Award Notices**

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the ATRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. 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 (i.e., assistance agreement).

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to *intragovernmental and intramural DOD organizations* will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to

the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

# **II.F.2. PI Changes and Award Transfers**

Unless otherwise restricted, changes in PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 7, Section F, for general information on organization or PI changes.

# **II.F.3.** Administrative and National Policy Requirements

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

Refer to the General Application Instructions, Appendix 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest <u>DoD R&D Terms and Conditions</u> and the <u>USAMRAA Research</u> <u>Terms and Conditions</u>: <u>Addendum to the DoD R&D Terms and Conditions</u> for further information.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local IACUC, Institutional Review Board, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

# II.F.4. Reporting

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report.

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template "Award Expiration Transition Plan," available on the eBRAP "Funding Opportunities & Forms" web page (<a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent five-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

# **II.G. Federal Awarding Agency Contacts**

# II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission

Phone: 301-682-5507

Email: <u>help@eBRAP.org</u>

# II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

# **II.H.** Other Information

# **II.H.1. Program Announcement and General Application Instructions Versions**

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

### **II.H.2.** Administrative Actions

After receipt of full applications, the following administrative actions may occur.

# II.H.2.a. Rejection

The following will result in administrative rejection of the full application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Animal Research Plan (Attachment 7) is missing for applications proposing animal research.

### II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

### II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the full application:

- An FY24 ATRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation.

  A list of the FY24 ATRP Programmatic Panel members can be found at <a href="https://cdmrp.health.mil/atrp/panels/panels24">https://cdmrp.health.mil/atrp/panels/panels24</a>.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or
  programmatic review companies. For FY24, the identities of the peer review contractor and
  the programmatic review contractor may be found at the CDMRP website
  (<a href="https://cdmrp.health.mil/about/2tierRevProcess">https://cdmrp.health.mil/about/2tierRevProcess</a>).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- A clinical trial is proposed.
- Clinical research is proposed.

### II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

# **II.H.3. Full Application Submission Checklist**

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance	
(Extramural submissions only)	
Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)	
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	П
Supporting Documentation – Attachment 2, upload as "Support.pdf"	
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	
Statement of Work – Attachment 5, upload as "SOW.pdf"	
Impact and Relevance to Military Health Statement – Attachment 6, upload as "Impact.pdf".	
Animal Research Plan - Attachment 7, upload as "AnimalResPlan.pdf"	
Representations (Extramural submissions only) – Attachment 8, upload as "RequiredReps.pdf"	
Suggested Intragovernmental/Intramural Budget Form ( <i>if applicable</i> ) – Attachment 9, upload as "IGBudget.pdf"	
Research & Related Personal Data	
Research & Related Senior/Key Person Profile (Expanded)	
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	
Research & Related Budget (Extramural submissions only) Include budget justification	
Budget (Intramural submissions only) Include budget justification	
Project/Performance Site Location(s) Form	
Research & Related Subaward Budget Attachment(s) Form (if applicable)	П

# APPENDIX 1: ACRONYM LIST

ACOS/R&D Associate Chief of Staff for Research and Development

ARRIVE Animal Research: Reporting In Vivo Experiments

ATRP Arthritis Research Program

CDMRP Congressionally Directed Medical Research Programs

CFR Code of Federal Regulations

DOD Department of Defense

DoDGARs Department of Defense Grant and Agreement Regulations

eBRAP Electronic Biomedical Research Application Portal

ET Eastern Time

FAD Funding Authorization Document

FRA Focused Research Award

FY Fiscal Year

IACUC Institutional Animal Care and Use Committee

LOI Letter of Intent

M Million

MIPR Military Interdepartmental Purchase Request

PDF Portable Document Format

PI Principal Investigator

SAM System for Award Management

SOW Statement of Work

UEI Unique Entity Identifier
URL Uniform Resource Locator

USAMRAA U.S. Army Medical Research Acquisition Activity

USAMRDC U.S. Army Medical Research and Development Command

USC United States Code

VA U.S. Department of Veterans Affairs