

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Arthritis Research Program

Clinical Research Award

Announcement Type: Initial

Funding Opportunity Number: HT942524ATRPCRA

**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.”

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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 <https://cdmrp.health.mil/atrp/default>.

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 multi-institutional 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 Clinical 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 Clinical Research Award (CRA) focus areas listed below.

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

- **Prevention:**
 - Clinically evaluate 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:**
 - Evaluate interventions or treatment strategies 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 Clinical Research Award mechanism is being offered for the first time in FY24.

II.B. Award Information

The FY24 ATRP CRA is intended to support clinical research that evaluates disease-specific factors and interventions. Research supported by this mechanism is intended to generate clinically useful evidence with potential to optimize patient outcomes and inform clinical care or policy. Research addressing **all types of arthritis** is encouraged including but not limited to osteoarthritis, post-traumatic arthritis, inflammatory arthritis, juvenile arthritis, or 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 the proposed research.

Applicants must address how the proposed research will impact patient care and reduce the burden of disease. It is expected that any research findings would benefit Service Members, Veterans, their Families, and the general public. To meet the intent of the award mechanism,

applications must specifically address at least one FY24 ATRP CRA focus area, listed in Section II.A.1, above.

Important aspects of this award mechanism include:

- **Impact:** The application should explicitly state how outcomes of the proposed research will have a significant impact on arthritis disease management, patient care, and quality of life.
- **Military Relevance:** The application should clearly describe 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](#)).
- **Post-Award Transition Plan:** The application should include the plan by which knowledge gained after successful completion of the award will be implemented in guidelines, communicated to relevant stakeholders, or move to the next phase of development.
- **Clinical Trial (CT) Option:** The FY24 ATRP CRA offers a clinical trial option that provides support to accommodate the costs of a clinical trial. Applications proposing only a clinical trial or proposing clinical research that includes a clinical trial within the period of performance may select the Clinical Trial Option. A description of the standard of care and justification of any control groups must be included in the application.

Preliminary data are required: Applications to the FY24 ATRP CRA must include preliminary and/or published data to support the proposed research project. 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 (<https://www.nature.com/nature/journal/v490/n7419/full/nature11556.html>). 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 CRA mechanism is intended to support clinical research or clinical trials and may not be used for preclinical or animal research. Applicants seeking funding for preclinical research or animal research should consider the FY24 ATRP Focused Research Award mechanism (Funding Opportunity Number: HT9425FY24ATRFRA).

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 CRA should not exceed **\$1.5M or \$3.0M (Clinical Trial Option)**. 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 \$6.0M to fund approximately two Clinical Research Award applications and one Clinical Research Award – Clinical Trial Option application. 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 [Section II.H.2, Administrative Actions](#), 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

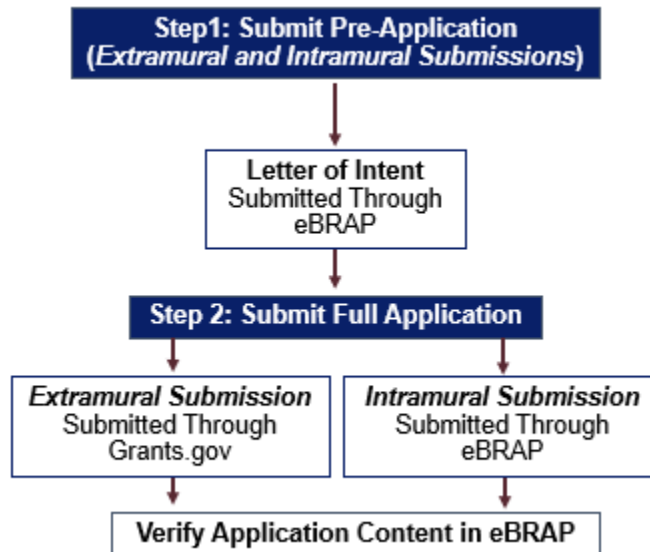
Submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a *full application* (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission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

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

eBRAP (<https://ebrap.org>) 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 (<https://grants.gov>) 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.

Application Submission Workflow



Extramural Submission: An application submitted by an [extramural organization](#) 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

HT942524ATRPCRA from Grants.gov (<https://grants.gov>). Full applications from extramural organizations **must** be submitted through Grants.gov.

Intramural Submission: An application submitted by an [intramural DOD organization](#) for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524ATRPCRA from the anticipated submission portal eBRAP (<https://ebrap.org>) 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 <https://cdmrp.health.mil/funding/researchDup>.

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 help@eBRAP.org 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:	Select Option:
Clinical Research Award	CRA
Clinical Research Award – Clinical Trial Option	CRA-CT

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 [Section II.H.3](#) 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 (12-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.

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.

Provide a literature review and analysis. Describe the preliminary studies and/or preclinical data that led to the development of the proposed clinical study. Provide a summary of other relevant, ongoing, planned, or completed clinical studies and describe how the proposed study differs.

- **Specific Aims**: Concisely describe the project’s aims.
- **Study Design**:
 - *For applications proposing clinical research*, describe the proposed clinical research in sufficient detail to evaluate its appropriateness and feasibility. Briefly describe and justify the study population and the inclusion and exclusion criteria that will be used to meet the needs of the proposed clinical research. Summarize the methods that will be used to recruit a sample of human subjects from the accessible populations (e.g. convenience, simple random, stratified random). Additional details should be provided in [Attachment 7: Human Subject Recruitment and Safety Procedures](#).

- *For applications proposing a clinical trial*, briefly describe the clinical trial to correlate the study design with the study objectives. Additional details regarding the clinical trial strategy should be provided in [Attachment 7: Human Subject Recruitment and Safety Procedures](#) and [Attachment 8: Clinical Trial Strategy Statement](#).
 - *For all applications*: If the proposed research involves access to active-duty military and/or VA patient populations and/or 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.
- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled. Include a power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.
- **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.
 - **Commercial Entity Letters of Commitment (if applicable; one-page limit per letter *is recommended*):** If the proposed study involves use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity indicating the availability of the product for the duration of the proposed clinical study, support for the proposed phase of research, and support for the indication to be tested.
 - **Intellectual Property:** Information can be found in the 2 CFR 200.315, “Intangible Property.”
 - **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instructions 3200.12](#). ***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. 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, including results from any screening or diagnostic tests performed as part of the study. In cases of national security or controlled unclassified information concerns, include a statement that the data cannot be made available to the public (e.g., “This data cannot be cleared for public release in accordance with the requirements in DoD Directive 5230.09.”). Refer to CDMRP’s Policy on Data & Resource Sharing located on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm> 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 active-duty military populations and/or 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 scientific rationale behind the proposed research project. 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 (five-page limit): Upload as “SOW.pdf”.** Refer to the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for the suggested SOW format and recommended strategies for assembling the SOW.

For the Clinical Research Award, refer to the “Example: Assembling a Clinical Research and/or Clinical Trial 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 (two-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 arthritis disease management, patient care practices, and quality of life, 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 lessen the impact of arthritis in the military, which may include its effect on Service Member recruitment, retention, and recovery.

- **Attachment 7: Human Subject Recruitment and Safety Procedures (no page limit): Upload as “HumSubProc.pdf”.** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
 - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. *Demonstrate that the research team has access to the proposed study population at each site, will maintain access throughout the proposed research, and describe the efforts that will be made to achieve accrual goals.* Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. *For clinical studies proposing inclusion of military populations, refer to the General Application Instructions, Appendix 4 for more information.*
 - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical research. Provide detailed justification for exclusions.
 - **Women and Minorities in the Study:** Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Describe the strategy for the inclusion of women and minorities in the clinical research appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.
 - **Inclusion Enrollment Plan:** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form that can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. For phase 3 clinical trials, use the form to describe plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity as appropriate for the scientific goals of the study. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.
 - **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification). Describe the recruitment process in detail. Address

- who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them. Address the availability of human subjects for the clinical study for each enrollment site. If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan. Describe the recruitment and advertisement materials. Discuss past efforts in recruiting human subjects from the target population for previous clinical studies (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Identify ongoing clinical studies that may compete for the same patient population and how they may impact enrollment progress.
- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.
 - ***For the proposed study, provide a draft, in English, of the Informed Consent Form.***
 - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the clinical study.
 - Include information regarding the timing and location of the consent process.
 - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
 - Address how privacy and time for decision-making will be provided and whether the potential human subject will be allowed to discuss the study with anyone before making a decision.
 - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
 - For applications proposing clinical trials, describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. **Note:** In compliance with 10 USC 980 (<https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>), the application must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial.

- **Assent:** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry.
- **Risks/Benefits Assessment:**
 - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. If applicable, any potential risk to the study personnel should be identified.
 - **Risk management and emergency response:** Appropriate to the study’s level of risk, describe how safety monitoring and reporting to the IRB and Regulatory Agency (if applicable) will be managed and conducted. Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values. Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the cost of such care.
 - **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.
- **Attachment 8: Clinical Trial Strategy Statement, *if applicable* (no page limit): Upload as “Clinical.pdf”. If funds for a clinical trial are requested, this attachment is required.**
 - Briefly describe the rationale for the proposed clinical trial. Provide a description of the intervention, its availability for the study, and the endpoints to be measured. Specify the standard of care and justify the control group to be utilized. Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
 - Describe how the proposed intervention addresses current clinical need(s) and compares with available interventions and/or standard of care.

- Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications, if applicable.
- If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically, identify the portions of the study that would be supported with funds from this award.
- If applicable, provide a mitigation strategy for any real or perceived financial COIs or biases.
- Provide detailed plans for initiating the clinical trial within the first year, including U.S. Food and Drug Administration (FDA) Investigational New Drug/Investigational Device Exemption application submission plans within 90 days of the award, if applicable. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Attachment 9: Post-Award Transition Plan (three-page limit): Upload as “Transition.pdf”.** Describe/discuss the methods and strategies proposed to move the intervention or finding to the next phase of development (late-stage clinical trials, commercialization, development of guidelines, and/or delivery to the civilian or military market) after successful completion of the award. Applicants are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development. The post-award transition plan should include the components listed below.
 - Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., specific industry partners, specific funding opportunities to be applied for, next-phase clinical studies, incorporation into clinical practice). Include a description of collaborations and other resources that will be used to provide continuity of development.
 - For knowledge products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. (A “knowledge product” is a non-materiel product that addresses an identified need, topic area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training, tools, or to support materiel solutions [systems to develop, acquire, provide, and sustain medical solutions and capabilities]; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)

- A brief schedule and milestones for transitioning the intervention (e.g., next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by the FDA).
 - Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government’s ability to access such products or technologies in the future.
 - A risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 10: Representations (*Extramural Submissions Only*): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
 - **Attachment 11: 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.
- **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.
 - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
 - **Intramural DOD Subaward:** Complete a separate “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as [Attachment 11](#).

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 (<https://www.sam.gov/content/home>) 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

Clinical Research Award:

The maximum period of performance is **4** years.

The application's total costs budgeted for the entire period of performance should not exceed **\$1.5M**. 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.

Clinical Research Award – Clinical Trial Option:

The maximum period of performance is **4** years.

The application's total costs budgeted for the entire period of performance should not exceed **\$3.0M**. 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 **4** years.

For this award mechanism, direct costs:

Must be requested for:

- Travel costs for up to two investigators to present project information or disseminate project results at one DOD-sponsored meeting (e.g., the Military Health System Research Symposium) during the period of performance in years 3 or 4 should be requested. For planning purposes, it should be assumed that the meeting will be held in the National Capital or Central Florida areas.

May be requested for (not all-inclusive):

- Research subject compensation and reimbursement for study-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving, and resources/equipment to enable participation).

Must not be requested for:

- Preclinical research costs
- Animal 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 of equal importance:

- **Impact**
 - How well the proposed study addresses the selected [FY24 ATRP CRA focus area](#).
 - To what degree the anticipated research outcomes of the proposed project will impact individuals who are living with arthritis.
 - To what degree the research may improve arthritis disease management, patient care practices, and quality of life.
 - How significantly the implementation of the anticipated study results may lessen the clinical burden of arthritis.
- **Research Strategy**
 - How well the scientific rationale for the proposed clinical research is supported by the preliminary or published data, critical review and analysis of the literature, and/or laboratory/preclinical evidence.
 - How well the study questions, specific aims, hypotheses and/or objective(s), experimental design, methods, data collection procedures, and analyses are designed to clearly answer the clinical objective and purpose.

- How well the application acknowledges potential challenges and addresses alternative approaches.
 - How well the inclusion/exclusion criteria and group assignment process meet the needs of the proposed clinical effort, if applicable.
 - How well plans to collect specimens and conduct laboratory evaluations are addressed, if applicable.
 - To what degree the data collection instruments (if applicable) and the data and research resources sharing plan are appropriate to the proposed study.
 - To what degree the statistical plan and power analysis are appropriate for the proposed project, as applicable.
 - If applicable, whether the mitigation of any real or perceived financial COIs or biases have been addressed.
- **Recruitment, Accrual, and Feasibility**
 - To what degree the number of human subjects to be enrolled within the study is reasonable based upon the proposed timeline, study procedures, study population, inclusion/exclusion criteria, and planned efforts to achieve accrual goals.
 - How well the application addresses the availability of human subjects for the clinical effort, access to the proposed human subject population, and the prospect of their participation.
 - The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical study.
 - How well the application identifies possible delays (e.g., slow/low enrollment, poor retention) and presents adequate mitigation plans to resolve them.
 - Whether the strategy for the inclusion of women and minorities is appropriate to the objectives of the study.
 - Whether the distribution of the proposed enrollment on the basis of sex/gender, race, and/or ethnicity is appropriate for the proposed research.
 - To what extent the proposed clinical study might affect the daily lives of the individual human subjects participating in the study (e.g., will human subjects still be able to take their regular medications while participating in the clinical study? Are human subjects required to stay overnight?).
 - How the level of risk to human subjects is minimized and how the safety monitoring and reporting plan is appropriate for the level of risk.

- To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
- To what degree privacy and confidentiality issues are appropriately considered.
- **Intervention** (*applicable only for applications proposing a clinical trial*)
 - Whether there is evidence of support, indicating availability of the intervention from its source, for the duration of the proposed clinical study (if applicable).
 - To what degree the intervention addresses current clinical need(s) described in the application.
 - How the intervention compares with currently available interventions and/or standards of care.
 - To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention.
 - How well research procedures are clearly delineated from routine clinical procedures.
 - Whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
- **Transition Plan**
 - Whether the strategy, schedule, and milestones for transition to the next phase of development, implementation, and/or commercialization (e.g., partners, next-phase clinical studies, incorporation into clinical practice, funding opportunities to be pursued if applicable) are realistic and reasonable.
 - For knowledge products, whether the proposed collaborations and other resources for providing continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journals publications, models, simulations, and applications are achievable.
 - How well the application identifies intellectual property ownership, demonstrates the appropriate access to all intellectual property rights necessary for development and/or commercialization, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent government access to products supported by this program announcement.
 - If applicable, whether the potential risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.

- **Personnel**

- To what degree the composition of the study team, including any external consultants or advisors (if using), is appropriate to accomplish the proposed work.
- Whether the levels of effort of the study team members are appropriate for successful conduct of the proposed research.

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 and/or clinical setting 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 [Section II.E.1.b, Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.health.mil/about/2tierRevProcess>.

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.

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

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 [DoD R&D Terms and Conditions](#) and the [USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions](#) for further information.

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 Institutional Animal Care and Use Committee, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

Clinical trials funded under this award mechanism are required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Funded studies are required to register the study in the National Institutes of Health clinical trial registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

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 (<https://ebrap.org/eBRAP/public/Program.htm>) 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.

Inclusion Enrollment Reporting: Enrollment reporting on the basis of sex/gender, race, and/or ethnicity using the PHS Inclusion Enrollment Report will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP.

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: help@eBRAP.org

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.
- Human Subject Recruitment and Safety Procedures ([Attachment 7](#)) is missing.
- Clinical Trial Strategy Statement ([Attachment 8](#)) is missing, *for applications proposing a clinical trial.*

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 <https://cdmrp.health.mil/atrp/panels/panels24>.*
- 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 (<https://cdmrp.health.mil/about/2tierRevProcess>).
- 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.
- The proposed research includes preclinical or animal research.

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 <i>(Extramural submissions only)</i>	<input type="checkbox"/>
Summary (Tab 1) and Application Contacts (Tab 2) <i>(Intramural submissions only)</i>	<input type="checkbox"/>
Attachments	
Project Narrative – Attachment 1, upload as “ProjectNarrative.pdf”	<input type="checkbox"/>
Supporting Documentation – Attachment 2, upload as “Support.pdf”	<input type="checkbox"/>
Technical Abstract – Attachment 3, upload as “TechAbs.pdf”	<input type="checkbox"/>
Lay Abstract – Attachment 4, upload as “LayAbs.pdf”	<input type="checkbox"/>
Statement of Work – Attachment 5, upload as “SOW.pdf”	<input type="checkbox"/>
Impact and Relevance to Military Health Statement – Attachment 6, upload as “Impact.pdf”	<input type="checkbox"/>
Human Subject Recruitment and Safety Procedures – Attachment 7, upload as “HumSubProc.pdf”	<input type="checkbox"/>
Clinical Trial Strategy Statement – Attachment 8, upload as “Clinical.pdf”	<input type="checkbox"/>
Post-Award Transition Plan – Attachment 9, upload as “Transition.pdf”.	<input type="checkbox"/>
Representations <i>(Extramural submissions only)</i> – Attachment 10, upload as “RequiredReps.pdf”	<input type="checkbox"/>
Suggested Intragovernmental/Intramural Budget Form <i>(if applicable)</i> – Attachment 11, upload as “IGBudget.pdf”	<input type="checkbox"/>
Research & Related Personal Data	<input type="checkbox"/>
Research & Related Senior/Key Person Profile (Expanded)	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>
Research & Related Budget <i>(Extramural submissions only)</i>	<input type="checkbox"/>
Include budget justification	<input type="checkbox"/>
Budget <i>(Intramural submissions only)</i>	<input type="checkbox"/>
Include budget justification	<input type="checkbox"/>
Project/Performance Site Location(s) Form	<input type="checkbox"/>
Research & Related Subaward Budget Attachment(s) Form <i>(if applicable)</i>	<input type="checkbox"/>

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ATRP	Arthritis Research Program
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CRA	Clinical Research Award
CT	Clinical Trial
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
FY	Fiscal Year
IRB	Institutional Review Board
LAR	Legally Authorized Representative
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PHS	Public Health Service
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