



Program Announcement for the Defense Health Agency

Autism Research Program Clinical Trial Award

Funding Opportunity Number: HT942526ARPCTA

Pre-Application Due: July 27, 2026

Application Due: October 22, 2026

This program announcement must be read in conjunction with the General Application Instructions, version [CD26_01](#).

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Before You Begin

- **Active [SAM.gov](#), [eBRAP.org](#) and [Grants.gov](#) registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read this funding opportunity announcement in the order it is written before beginning to prepare application materials.** It is the responsibility of the applicant to determine whether the proposed research meets the intent of this funding opportunity and that all parties meet eligibility requirements.
- **To support application preparation, additional resources are available** including an application process [FAQ](#), a [Guide for Intragovernmental & Intramural Applicants](#) and a [CDMRP Video Series](#) detailing the application process.

Who to Contact for Support

eBRAP Help Desk

301-682-5507
help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

Grants.gov Support Center

800-518-4726
International: 1-606-545-5035
support@grants.gov

Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing the Alt + left arrow keys (Windows) or command + left arrow keys (Macintosh) on your keyboard.

Click  to be taken to additional guidance and instructions within the General Application Instructions (GAI).

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1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2026 (FY26) Autism Research Program (ARP) Clinical Trial Award supports the rapid implementation of clinical trials with the potential to have a significant impact on the treatment or management of autism. Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs or biologics), devices, clinical guidance and/or emerging approaches and technologies. Proposed projects may range from small proof-of-concept trials (e.g., pilot, first-in-human, phase 0) to demonstrate the feasibility or inform the design of more advanced trials through large-scale trials to determine efficacy in relevant patient populations.

Distinctive Features: *Applications are strongly encouraged to address one of the [FY26 ARP Clinical Trial Award Areas of Interest](#).*

Partnering Principal Investigator (PI) Option for Early-Career Investigator: The FY26 Clinical Trial Award mechanism is offering a higher level of funding for applications that propose to partner an experienced PI (i.e., Initiating PI) with an Early-Career Investigator (i.e., Partnering PI) wishing to pursue a career in autism clinical trial research.

FY26 Clinical Trial Award submissions are required to include community collaborations to optimize research impact. Research teams are therefore required to establish and utilize effective and equitable collaborations and partnerships with community members to maximize the translational and impact potential of the proposed research. Applications to the FY26 ARP Clinical Trial Award are expected to name at least one community partner (e.g., Autistic individual or caregiver, representatives of community-based organizations) who will provide advice and consultation throughout the planning and implementation of the research project. Interactions with other team members should be well integrated and ongoing, not limited to attending seminars and semi-annual meetings (see [Attachment 12, Community Collaboration Plan](#)).

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly \$3.25 million (M) to fund approximately one Clinical Trial Award with a total cost cap of \$1.50M and one Clinical Trial Award - Partnering PI Option for Early Career Investigator application with a total cost cap of \$1.75M. The maximum period of performance is 4 years. It is anticipated that awards made from this FY26 funding opportunity will be funded with FY26 funds, which will expire for use on September 30, 2032. Awards supported with FY26 funds will be made no later than September 30, 2027.

Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), July 27, 2026
- **Invitation to Submit an Application:** August 28, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, October 22, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, October 27, 2026
- **Peer Review:** December 2026
- **Programmatic Review:** February 2027

Announcement Type: Initial

Funding Opportunity Number: HT942526ARPCTA

Assistance Listing Number: 12.420

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2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

[Extramural](#) and [intramural U.S. Department of War \(DOW\)](#) organizations are eligible to apply, ***including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities.***

2.1.2. Principal Investigator

Independent investigators affiliated with an eligible organization are eligible to be named as PI on the application, regardless of ethnicity, nationality or citizenship status

For application submissions under the **Single Principal Investigator Option**: Investigators must be at or above the level of Assistant Professor (or equivalent) to be named by the organization as the PI on the application.

Industry titles may not be analogous to a faculty hierarchy in academia. For industry, investigators at or above an independent scientist level may be named by the organization as the PI on the application.

For application submissions under the **Partnering PI Option for Early-Career Investigator**:

- The **Initiating PI (Mentor)** named by the organization as the PI on the application must be at or above the level of Assistant Professor (or equivalent).
- By the full application submission date, **the Partnering PI (Early-Career Investigator)** must:
 - Be in a current postdoctoral training position or have completed postdoctoral training.
 - Be no more than seven years from the receipt of a terminal degree (excluding time spent in residency or on family medical leave). Lapses in research time or appointments as denoted in the biographical sketch may be articulated in the application.
- The Partnering PI (Early-Career Investigator) must contribute at least 50% effort for the proposed research that would be supported by this award.

It is *not* required that the Partnering PI (Early-Career Investigator) and the Initiating PI (Mentor) be located at the same institution.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

Awards are made to eligible **organizations**, not to individuals. Refer to the General Application Guidelines (GAI) for additional [recipient qualification requirements](#).

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3. Program Description

The Defense Health Agency Contracting Activity (DHACA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP is the program office managing this FY26 funding opportunity as part of the Autism Research Program (ARP). The CDMRP is located within the Defense Health Agency Research and Development (DHA R&D), which is a part of the Department of Defense, DOD, herein referred to using the secondary title Department of War, DOW. Congress initiated the ARP in 2007 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the ARP from FY07 through FY24 totaled \$164.4 M. The FY26 appropriation is \$8.0M.

The ARP's vision is to improve the lives of individuals with autism and their families, now and in their future.

Research funded by the FY26 ARP should be responsive to the needs of people with autism, their families and/or caregivers. Researchers are therefore encouraged to establish and utilize effective collaborations and partnerships with community members to maximize the translational and impact potential of the proposed research.

3.1. Award History

The ARP Clinical Trial Award mechanism was first offered in FY09. Since then, 189 Clinical Trial Award applications were received, and 32 were recommended for funding.

3.2. Intent of the Clinical Trial Award

The ARP Clinical Trial Award supports the rapid execution and analysis of clinical trials with the potential to have a significant impact on the treatment or management of autism. Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs, biologics or medical devices), clinical guidance and/or emerging approaches and technologies. Proposed projects may range from small proof-of-concept trials (i.e., pilot, first-in-human, phase 0) to demonstrate the feasibility or inform the design of more advanced trials through large-scale trials to determine efficacy in relevant patient populations.

3.2.1. Areas of Interest for the CTA

To meet the intent of the funding opportunity the ARP encourages applications that address critical needs of the autism community in one or more of the FY26 ARP Clinical Trial Award Areas of Interest:

- Create tools and strategies to increase the speed of the dissemination/implementation of evidence-based practices and interventions in community-based settings
- Determinates of diagnosis, treatment efficacy and service delivery
- Factors impacting quality of life for current and former military families
- Health care provider-focused training or tools to improve health care delivery for Autistic individuals across the lifespan and the continuum of care (i.e., primary care, urgent/emergent care and disaster relief)
- Improve diagnosis and access to services across the lifespan

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- Interventions to support Autistic individuals and their families, including key transitions into adulthood and across their lifespan
- Mental health issues (such as grief, masking, suicide risk, trauma, etc.) or disorders in Autistic individuals
- Non-pharmacological therapies for the core symptoms of autism or to alleviate co-occurring conditions (including pain, sleeping, eating)
- Pharmacological, genetic, and other biological treatments for the core symptoms of autism or to alleviate co-occurring conditions
- **(New for FY26)** Physical health, mental health, and related quality-of-life issues in aging Autistic adults
- **(New for FY26)** Sexual health, sexual education, and reproductive health for Autistic individuals
- Uncovering new advances using a strength-based model
- Understanding heterogeneity in treatment response, including identification of psychosocial or biological factors that (1) impact treatment outcomes or (2) can be used to prospectively identify treatments that are most likely to benefit particular subgroups of individuals

3.2.2. Key Elements for the CTA

Partnering PI Option for Early-Career Investigator: The FY26 Clinical Trial Award mechanism includes an option for a higher level of funding for applications that propose to partner an experienced PI (i.e., Initiating PI) with an Early-Career Investigator (i.e., Partnering PI) wishing to pursue a career in autism clinical trial research. The Initiating PI on the Clinical Trial Award must mentor the Early-Career Investigator (Partnering PI) to promote their career development in clinical trial research. The Early-Career Investigator must meet specific eligibility criteria as described in [Section 2. Eligibility Information](#). The Initiating PI will be responsible for the majority of the administrative tasks associated with application submission. The Initiating and Partnering PIs each have different submission requirements, as described in [Section 5.3, Submission Instructions](#); however, both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements.

When developing applications to the ARP Clinical Trial Award mechanism, the ARP strongly encourages applicants to provide sufficient evidence to demonstrate the following key considerations.

- **Clinical Trial Start Date:** The proposed clinical trial is expected to begin no later than 12 months after the award date or 18 months after the award date for studies regulated by the Regulatory Agency.
- **Impact:** The proposed intervention(s) to be tested should offer significant potential impact for Autistic individuals.
- **Preliminary Data Are Required:** Inclusion of preliminary data relevant to the proposed clinical trial is required.
- **Study Population:** The application should demonstrate the availability of and access to a suitable patient population that will support a meaningful outcome for the study. The

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application should include a discussion of how accrual goals will be achieved, as well as the strategy for inclusion of women and minorities in the clinical trial appropriate to the objectives of the study. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, sex, ethnicity or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

- **Intervention Availability:** The application should demonstrate the documented availability of and access to the drug/compound, device and/or other materials needed, as appropriate, for the proposed duration of the study.
- **Personnel and Environment:** The application should demonstrate the study team's expertise and experience in all aspects of conducting clinical trials, including appropriate statistical analysis, knowledge of U.S. Food and Drug Administration (FDA) processes (if applicable), and data management. The application should include a study coordinator(s) who will guide the clinical protocol through the local IRB of record and other federal agency regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate participant accrual. The application should show strong institutional support and, if applicable, a commitment to serve as the FDA regulatory sponsor, ensuring all sponsor responsibilities
- **Statistical Analysis and Data Analysis:** The application should include a clearly articulated statistical analysis plan, a power analysis reflecting sample size projections that will answer the objectives of the study, and a data management plan that includes use of an appropriate database to safeguard and maintain the integrity of the data.
- The application should include a transition plan (including potential funding and resources) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful completion of the FY26 ARP Clinical Trial Award.

3.2.3. Other Important Considerations for the CTA

Funding from this award mechanism must support a [clinical trial](#). Preclinical research is not supported in this funding opportunity.

FY26 Clinical Trial Award submissions are required to include community collaborations to optimize research impact (see [Attachment 12, Community Collaboration Plan](#)).

Applicants seeking funding for research that does not meet the definition of a clinical trial should consider other FY26 ARP funding opportunities that may be more appropriate for such research.

An informational resource for preparing an application, the [Human Subject Research Resource](#), is available on the CDMRP website.

The proposed clinical trial is expected to begin no later than 12 months after the award date or 18 months after the award date for studies regulated by the Regulatory Agency. Unless otherwise noted, for the purposes of this funding opportunity, Regulatory Agency refers to the FDA or any equivalent international Regulatory Agency.

If an Investigational New Drug (IND) application, Investigational Device Exemption (IDE), or equivalent, is required, a regulatory application ***must be submitted to the relevant Regulatory Agency by the Clinical Trial Award application submission deadline***. The regulatory application should be specific to the product and indication to be tested in the proposed clinical trial.

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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, such as those described in the [STROBE](#), [CONSORT](#), [SPIRIT](#) and [ARRIVE 2.0](#) guidelines.

Applications from investigators within the DOW and applications involving multidisciplinary collaborations among academia, industry, the DOW, the U.S. Department of Veterans Affairs (VA) and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, their Families and the American Public. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

3.3. Funding Instrument

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

3.4. Funding Details

Period of Performance: The maximum period of performance is **4** years.

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **\$1.5M for a Single PI and \$1.75M for the Partnering PI Option for Early-Career Investigator**. 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.

The appropriateness of the budget for the proposed research will be assessed during peer review.

A separate award will be made to each PI's organization.

The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

Any application that requests the higher level of funding and that does not include a collaborative PI will have its budget reduced as appropriate.

Direct Cost Restrictions: For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Travel between collaborating organizations.
- Costs for two investigators to travel to two scientific/technical meetings per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the ARP Clinical Trial Award.

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- Research subject compensation and reimbursement for trial-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:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.

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4. Application Contents and Format

4.1. Application Overview

Application submission is a two-step process requiring both a **pre-application** submitted via the Electronic Biomedical Research Application Portal ([eBRAP](#)) and a **full application** submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOW organizations submitting a full application should follow instructions for submission through eBRAP.



Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.



4.2. Pre-Application Components

The Initiating PI must submit the following pre-application components.

Upload documents as individual PDF files unless otherwise noted. Files must comply with the [formatting guidelines](#) listed in the GAI.

- **Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.


The Preproposal Narrative should include the following:

- **Research Idea:** Concisely state the project's objective and specific aims. State the [FY26 ARP Clinical Trial Award Area\(s\) of Interest](#) to be studied. If the proposed clinical trial does not address a Clinical Trial Award area of interest, provide justification that the proposed clinical trial addresses another important problem with respect to Autistic individuals. Briefly describe the proposed project and the population(s) that will be enrolled in the study. Briefly describe the preliminary data and rationale including literature references supporting the proposed clinical trial. Identify the population, access to the population, recruitment goals, including a brief description of the statistical plan. State how this project meets the vision of the ARP.
- **Intervention:** Describe the intervention to be tested, the outcome measures, participant inclusion and exclusion criteria, and how it is applicable to the study population. Describe the feasibility in utilizing the intervention, any potential risks, and how the potential benefits outweigh the risks of the intervention to be tested.
- **Clinical Impact:** Describe the potential impact of this study on the outcomes of Autistic individuals and, if applicable, their families/caregivers.
- **Personnel:** State how the background, clinical trial experience, and autism expertise of the clinical team are appropriate to accomplish the proposed trial (e.g., statistical expertise, expertise in autism research and clinical studies).
- **Partnering PI Option for Early-Career Investigator (if applicable):** Describe how the Initiating PI (Mentor) is positioned to provide the Partnering PI (Early-Career Investigator) with mentorship toward a successful career in autism clinical trial research.

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Briefly describe the researcher development plan and how it will contribute to fostering the Partnering PI's career development as an autism clinical trial researcher.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to the following:
 - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
 - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
 - **Key Personnel Biographical Sketches:** *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished. 

4.3. Full Application Components

Applicants **must** receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

Partnering PI Option for Early-Career Investigator: The CDMRP requires separate full application package submissions for the Initiating PI and the Partnering PI, even if the PIs are located within the same organization. The application submission process for the Partnering PI uses an [abbreviated full application package](#).

4.3.1. Full Application Components for the PI or Initiating PI


Each application submission must include the completed full application package for this program announcement. See [Appendix 1](#) for a checklist of the full application components.

- (a) **SF424 Research & Related Application for Federal Assistance Form (*Grants.gov submissions only*):** 

IMPORTANT: *When completing the SF424 R&R, enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier.*

- (b) **Attachments:**

Each attachment of the full application components must be uploaded as an individual file in the format specified and in accordance with the [formatting guidelines](#) in the GAI.

- **Attachment 1: Project Narrative (20-page limit):** Upload as “ProjectNarrative.pdf”. 
- The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) 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.

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The Project Narrative is NOT the formal clinical trial protocol. Instead, all essential elements of the proposed clinical trial necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 6-10 described below. Failure to submit these attachments as part of the application package will result in rejection of the entire application.

Describe the proposed project in detail using the outline below. It should be clear from this description that the proposed study meets the definition of a [clinical trial](#).


- **Background:** Describe in detail the scientific rationale for the study. Provide a review and analysis of the available literature and completed/ongoing studies relevant to the proposed clinical trial.
 - Describe the preliminary studies and/or preclinical data that support the proposed clinical trial.
 - Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.
 - Provide a summary of other relevant ongoing, planned, or completed clinical trials and describe how the proposed study differs.

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(s) of prior funding. Identify the specific portions of the study that will be supported with funds from this award.

- **Objectives, Specific Aims and Hypotheses:** Describe the purpose of the proposed study with detailed objectives. State the hypothesis/research question to be tested in the proposed clinical trial and detail the specific aims that will address the hypothesis/research question.
- **Study Design:** Describe the proposed clinical trial in sufficient detail to evaluate its appropriateness and feasibility, relating to both the scientific success of the study and setting reasonable expectations for what study participants will experience.
 - Describe the type of study to be performed. Outline the proposed clinical trial methodology and study variables in sufficient detail to demonstrate a clear course of action and justification. Describe the interaction with the human subject, including the study intervention that they will experience, and include the dose and administration route. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the study participant will experience. Consult appropriate [guidelines](#) to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.
 - Provide a schedule (e.g., flowchart or diagram) of study intervention(s), evaluation(s), and follow-up procedures, including, if applicable, the biospecimen that will be collected along with the collection schedule and amount. Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions). Define each arm/study group of the proposed trial, if applicable, and describe how group assignment will occur. Include a description of controls, as appropriate. Specify the approximate number of study participants to be enrolled. Indicate whether subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.

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- Define all endpoints/outcome measures relevant to the objectives of the study, explain why they were chosen, and describe how, when, and where they will be measured. Include all evaluations that will be made for study purposes. If questionnaires or other research data collection instruments will be used, include a copy of them within [Attachment 6: Intervention](#). Describe the reliability and validity of the selected endpoint/outcome measure and evaluation, along with the applicable quality standards. Explain how the results of evaluations and/or data collection instruments will be used to meet the objectives of the study (or to monitor safety of human subjects).
 - Briefly describe the study population and the inclusion and exclusion criteria that will be used to meet the needs of the proposed clinical trial. Additional details should be provided in [Attachment 7: Study Population Recruitment and Safety Plan](#).
 - **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.
 - Include a complete power analysis to demonstrate that the proposed clinical trial’s anticipated sample size is appropriate to meet the objectives of the study. Describe all clinical and statistical justifications and assumptions that support the sample size calculations. Explain any anticipated subgroup analyses and demonstrate that such analyses will be appropriately powered.
 - **Pitfalls and Mitigation Strategy:** Describe potential challenges and discuss alternative methods/approaches that may be employed to overcome them.
 - **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** 
- There are no page limits for these components unless otherwise noted. Include only 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 in the Project Narrative using a standard reference format (include URLs, if available).
 - **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; include 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 the original or present government award under which the facilities or equipment items are now accountable. There is not a standardized 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.

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- **Letters of Support (two-page limit per letter is recommended):** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work for the duration of the proposed clinical trial. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet [eligibility criteria](#). If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOW collaborator(s) and/or access to military populations, databases or DOW resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or an individual designated by the VA Facility Director(s), confirming access to VA patients, resources and/or VA research space.
- **Research Sharing Plan:** Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe the mechanism (e.g., direct sharing, repository, mixed mode) by which data and resources generated during the period of performance will be shared with the research community and other affected communities, including clinical trial participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial will be archived, if applicable. Identify and provide the rationale for any data or resources that will not be shared (e.g. for intellectual property, feasibility, cost, or other considerations). The plan should also protect participant privacy, confidential and proprietary data, and performer/third-party intellectual property. Provide a milestone plan for disseminating data/results including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

Do not submit a copy of the National Institutes of Health (NIH) Data Management and Sharing Plan or duplicate the Data Management Plan, which will be requested only after a recommendation for funding is made.

Refer to the [CDMRP Directive on Sharing Data and Research Resources](#) for more information about the CDMRP's expectations for making data and research resources publicly available.

- **Commercial Entity Letters of Commitment (if applicable):** 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 trial, support for the proposed phase of research, and support for the indication to be tested.
- **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.

The following supporting documents are required **only** for application submissions under the **Partnering PI Option for Early-Career Investigator**:

- **Early-Career Investigator Statement (one page recommended):**
The Early-Career Investigator Statement is expected to be written by the Partnering PI (Early-Career Investigator) while also showing evidence of appropriate direction from the Initiating PI, who will serve as the Mentor for this project.

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- The Early-Career Investigator should describe their accomplishments (i.e., academic performance, awards, honors, and/or previous publications and funding) and how they are indicative of potential for a successful, productive, independent career in autism clinical trial research.
- The Early-Career Investigator should describe their career goals and how the proposed research project and mentored research experience will promote their career development in autism clinical trial research. The Early-Career Investigator should discuss their career/research plans after the completion of this award.
- **Researcher Development Plan (if applicable) (two pages recommended):**

The Researcher Development Plan is expected to be written by the Initiating PI (Mentor) and articulate the following:

 - Clearly describe and outline the individualized Researcher Development Plan, including proposed training (e.g., coursework, mentorship) to support the development of the Early-Career Investigator’s clinical trial research skills.
 - Highlight the unique features of this plan as it pertains specifically to autism clinical trial research.
 - Clearly articulate a strategy for the Early-Career Investigator to develop the necessary skills, competence, and expertise to pursue a promising career in autism clinical trial research.
 - Describe the Initiating PI’s experience in autism clinical trial research and mentoring, as demonstrated by a record of active funding, recent publications, and successful mentorship.
 - Describe how the Initiating PI is positioned to mentor the Early-Career Investigator toward a successful career in autism clinical trial research.
 - Describe how the Researcher Development Plan is supported by the research environment, including a description of ongoing autism research at the institution(s). Include information on collaborations with other investigators.
 - Describe the Early-Career Investigator’s role in the proposed research project.
- **Partnering PI Option for Early-Career Investigator Letter of Eligibility (if applicable) (one-page limit):** Use the Clinical Trial Award Early-Career Investigator Eligibility Statement Template (available for download on the Full Announcement page in Grants.gov and under Funding Opportunities and Forms in eBRAP) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met at the application submission deadline.
- **Transcripts (if applicable) (no page limit):** Include a copy of the Early-Career Investigator’s transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts. If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), complete and include the Academic Statement (available for download on the “Full Announcement” page in [Grants.gov](#)) in place of the transcript.

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- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** 

Write the technical abstract using the outline below. Clarity and completeness within the space limits are highly important.

- **Background:** Present the ideas and rationale behind the proposed clinical trial.
- **Hypothesis/Objective(s):** State the objective of the proposed clinical trial and the hypothesis/research question to be addressed.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design, including appropriate controls.
- **Clinical Impact:** Briefly describe how the proposed clinical trial will have a significant impact on the research field and/or treatment or management of autism.
- **Military Relevance:** Describe how the study is relevant to military health.

- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** 

The lay abstract should address the points outlined below *in a manner that is readily understood by readers without a background in science or medicine*. Avoid overuse of scientific jargon, acronyms and abbreviations. **Do not duplicate the technical abstract.**

- Summarize the objectives and rationale for the proposed clinical trial.
- Describe the intervention(s).
- What population will the research help, and how will it help them?
- What are the expected clinical applications, and potential risks of the anticipated outcomes?
- Describe the ultimate applicability and impact of the proposed study and the anticipated outcomes to advancing research, patient care and/or quality of life?
- State which [FY26 ARP Clinical Trial Award Area\(s\) of Interest](#) will be addressed in the study or provide justification that the trial addresses another important problem or critical issue with respect to Autistic individuals
- Describe the potential benefit of the proposed study and the anticipated outcomes to Service Members, Veterans and/or their Families.

- **Attachment 5: Statement of Work (four-page limit): Upload as “SOW.pdf”.** 
Refer to eBRAP for the [Suggested SOW Format](#).

For guidance on preparing the SOW, refer to the [Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work](#). Include milestones for data or research resource(s) sharing.

Partnering PI Option: Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and the Partnering PI should be clearly noted for each task.

- **Attachment 6: Intervention (no page limit): Upload as “Intervention.pdf”.** The Intervention attachment should include the components listed below.

- **Description of the Intervention:** Identify the intervention to be tested and describe the particular outcomes. Describe how the intervention addresses current clinical

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needs and how it compares with currently available interventions and/or standards of care. As applicable, the description of the intervention should include the following components: complete name and composition, storage and handling information, source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed. Description of devices should include general concept of design, detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for conduct of the clinical trial. Summarize key preclinical pharmacological findings, dosage studies and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.

- **Study Procedures:** Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention). Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions). Clearly delineate research procedures from routine clinical procedures. Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study. Discuss how compliance with current Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) guidelines and other regulatory considerations will be established, monitored, and maintained, as applicable.
- **Laboratory Evaluations:** State the biospecimen that will be collected along with the collection schedule and amount. Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects). Describe the specimen storage plan, including location of storage, how long specimens will be stored, any special conditions required, labeling and specimen disposition. Outline the actions to be taken to allow the use of stored specimens in future research studies, if applicable. Identify the laboratory performing each evaluation, the applicable quality standard, and any special precautions that should be taken in handling the samples. If transport of samples is required, describe provisions for ensuring proper storage during transport.
- **Questionnaires and Other Research Data Collection Instruments:** Include a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides or other instruments. For each instrument, describe how the information collected is related to the objectives of the study. Describe how and when the instrument(s) will be administered. Describe how the instrument(s) will be adapted to the subject population, if applicable.
- **Clinical Monitoring Plan:** Describe how the study will be conducted by and monitored for current ICH E6 (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) Good Clinical Practice (GCP) compliance by an independent clinical trial monitor (or clinical research associate). The monitoring plan should describe the types of monitoring visits to be conducted, the intervals (based on level of risk), how corrective actions will be reported to the Sponsor and PI and how they will be corrected and prevented by the clinical trial site/PI.

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- **Attachment 7: Study Population Recruitment and Safety Plan (no page limit): Upload as “StudyPopPlan.pdf”.** Include the components listed below.
 - **Enrollment Distribution:** Provide anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race and ethnicity using the [Public Health Service \(PHS\) Inclusion Enrollment Report](#). The enrollment table(s) should be appropriate to the objectives of the study.
 - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. If limiting inclusion by age, race, ethnicity or sex, provide strong rationale based on justification from scientific literature, preliminary data or other relevant considerations. 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. Describe how the study population represents the population anticipated to benefit from the intervention.
 - **Study Population Availability:** Demonstrate that the research team has access to the proposed study population at each site. Describe the approximate number, pertinent demographic information and other relevant characteristics of the study population at each enrollment site. Indicate whether the actual size of available study population may be affected by ongoing clinical trials that compete for the same population. If the proposed research involves access to military and/or VA patient populations and/or DOW 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. Also include a plan for obtaining any required data sharing, memorandum of understanding or other agreements required to access and publish data. Refer to the GAI, [Appendix 4](#), for additional considerations.
 - **Recruitment and Retention Process:** Explain methods for identification of potential study participants (e.g., medical record review, obtaining sampling lists, health care provider identification). Describe the recruitment process in detail; address who will identify potential study participants, who will recruit them, and what methods will be used to recruit them. Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study. If study participants will be compensated, include a detailed description of and justification for the compensation plan. Describe the methods that will be employed to retain participants within the study. Discuss past efforts in recruiting and retaining study participants for previous clinical trials (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. Estimate the potential for participant loss to follow up and how such loss will be handled/mitigated. Indicate whether the study team has considered barriers to clinical trial participation and, if applicable, how the team aims to mitigate or overcome these barriers.
 - **Women and Minorities Recruitment/Retention Strategy:** Describe the strategy for recruitment, enrollment and retention specific to women and minorities in the clinical trial appropriate to the objectives of the study.
 - **Informed Consent Process:** Specifically describe the plan for obtaining informed consent from study participants; include information regarding the timing and location of the consent process. If minors or other populations that cannot provide informed

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consent are included in the proposed clinical trial, describe the plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent. [Appendix 6](#) of the GAI contains additional considerations unique to DOW-sponsored research.

– **Risks/Benefits Assessment:**

- **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Address special precautions to be taken by the human subjects before, during and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention). If applicable, identify any potential risk to the study personnel.
- **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. 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 costs 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: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** Answer the following questions and provide supporting documentation as applicable.

- State the product/intervention name.

For products/interventions that do not require regulation by a Regulatory Agency:

- Provide evidence that the clinical trial does not require regulation by a Regulatory Agency. Submissions providing "not applicable," "none," or similar responses do not satisfy this request. No further information about this attachment is required.

For products that require regulation by a Regulatory Agency:

- Describe the overall regulatory strategy and product development plan that will be performed during the project's period of performance to support the planned product indication/label. Include, as appropriate, a description of the regulatory application submission strategy.
 - State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States. If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication.
 - If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use and whether an IND or IDE application was submitted. ***If an IND or IDE is required, the application must be submitted to the FDA prior to the FY26 ARP Clinical Trial Award application submission deadline.*** The IND or IDE should be specific for the investigational product (i.e., not a

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derivative or alternate version of the product) and include an indication to be tested in the proposed clinical trial. Provide the date of submission, the application number and a copy of the FDA letter acknowledging the submission.

- Provide a summary of any meetings the research team had with regulatory agencies or consultants regarding the proposed research; include key outcomes, action items and recommendations. If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.
 - If the clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).
- **Attachment 9: Study Personnel and Organization (no page limit): Start each document on a new page. Combine into one document and upload as “Personnel.pdf”.** The Study Personnel and Organization attachment should include the components listed below.
 - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers, and/or departments, and name each person’s position on the project; include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate, including the location of the organization. If applicable, identify the Regulatory Agency sponsor and any external consultants or other experts who will assist with Regulatory Agency sponsor applications. While there is no specified format for this information, a table(s) or diagram is recommended.
 - **Study Personnel Description:** Describe the composition of the study team in enough detail to determine whether the team includes relevant subject matter expertise to accomplish the proposed work. Include the roles of individuals named in the organizational chart along with any external consultants or advisors who will provide critical guidance and input to the study team (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate). Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed clinical trial.
 - **Study Management Plan:** Describe the day-to-day management of the proposed clinical trial. Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial involves more than one institution, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. If applicable, describe how communication and data transfer between/among the collaborating institutions will occur, as well as how data, specimens and/or imaging products obtained during the study will be handled and shared. Provide a plan for resolving intellectual and material property issues among participating organizations.
 - **Attachment 10: Post-Award Transition Plan (three-page limit): Upload as “Transition.pdf”.** Discuss the anticipated methods and strategies necessary to move the anticipated research outcome (e.g., intervention, product, methodology, finding) to the next phase of development (e.g., clinical trials, commercialization and/or delivery to the civilian or military market), assuming a positive outcome from the proposed clinical

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trial. Investigators are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. Applicants are encouraged to explore developing relationships with industry and/or other funding agencies or investors to facilitate moving the product into the next phase of development when preparing the transition plan. ***The post-award transition plan should:***

- Name the project's anticipated research outcomes including knowledge products and/or clinical products for development. A "knowledge product" is a non-material product that aims to transition into medical practice, training, tools or to support material solutions; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.
- Include a timeline with defined milestones describing the logical next steps to advance the research outcome to the next stage of clinical development/implementation/dissemination. Include steps regarding Regulatory Agency approval as appropriate.
- Describe collaborations and other resources (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources) that are in place or will be established to execute the steps described above. Include a discussion of the funding strategy necessary to transition the research outcome to the next level of investigation, development, and/or commercialization. The discussion should include potential opportunities for securing funding through commercial sponsorship, venture capital, federal or nonfederal funding opportunities, or other relevant resources.
- As appropriate, discuss ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award. Include a plan for resolving intellectual and material property issues among participating organizations. If the intellectual property rights are not owned by the applicant, PI or a member of the study team, describe the planned next steps necessary to make the product available to the target population.
- **Attachment 11: Clinical Impact Statement (two-page limit): Upload as "Impact.pdf"**. The impact statement summarizes the potential short- and long-term impact of the proposed clinical trial. The statement should address the points outlined below written ***in a manner that will be readily understood by readers without a background in science or medicine.***
 - Summarize the potential benefit(s) of the intervention and/or research outcome of the proposed clinical trial as it relates to the [FY26 ARP Clinical Trial Award Area\(s\) of Interest](#).
 - Detail the anticipated research outcome(s) that will be directly attributed to the results of the proposed clinical trial and describe the anticipated benefits of these outcomes for individuals and the research field.
 - Explain the long-range vision for how implementation/dissemination of the intervention and/or research outcome(s) will improve patient care and/or quality of life for the target population. Describe how the intervention represents an improvement over currently available interventions and/or standards of care.
 - Describe any potential challenges that might limit the impact of the proposed clinical trial, including barriers to implementation or acceptance by users.

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- **Attachment 12: Community Collaboration Plan: Combine and upload as a single file named “Collaboration.pdf”.** Refer to Section 3.2.3 for more details regarding the community collaboration requirement. ***This attachment must be written in a manner that will be readily understood by the general public, especially those without a background in science or medicine.***
 - **Collaborative Research Statement (two-page limit):** Describe the collaborative research approach that will be used. Detail when and how the approach will be used within the research project, how input will be meaningfully incorporated into the research design, execution, and dissemination, and explain how this best serves the Autism community.
 - Name the individuals(s) participating and describe how the community collaborator(s) are connected to the study population(s).
 - Describe any training, co-learning, or capacity-building activities that will be provided to both scientific researchers and community members on collaborative research approaches, decision-making and equitable participation.
 - **Letters of Community Collaboration (suggested two-page limit per letter):** Provide a letter signed by each community partner confirming their role and commitment to participate on the research team. If a community-based organization will be engaged, the letter of commitment should be signed by BOTH the organization point of contact leading the engagement and the organization’s leadership endorsing the collaboration. The letter should mention why the qualifications and background of the individual will benefit the proposed research project
- **Attachment 13: National Institute of Mental Health Data Archive (NDA) Submission Plan (two-page limit): Upload as “NDA.pdf”.** Provide a plan for submission of human subject data to the NDA, including information on security of personal information (Health Insurance Portability and Accountability Act, also known as HIPAA) and data sharing for the bioinformatics platform. Consult the [NDA website](#) for additional information.
- **Attachment 14: Representations (*Grants.gov submissions only*): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the [Required Representations](#) document available on eBRAP. 
- **Attachment 15: Suggested Intragovernmental/Intramural Budget Form (*if applicable*): Upload as “IGBudget.pdf”.** If an [intramural DOW organization](#) will be a collaborator in the performance of the project, complete a separate budget for that organization using the [Suggested Intragovernmental/Intramural Budget](#) form available on eBRAP. 

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(c) Additional Application Materials:

The following are additional forms for application submission. Follow the instructions specific to the submission portal, as found within the GAI.



Grants.gov



eBRAP.org

i. Research & Related Senior/Key Person Profile (Expanded)

- **Biographical Sketch**
- **Current/Pending Support**

Intragovernmental applicants must include their internally supported research and development programs.

ii. Research & Related Budget

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s), or vice versa, even if they are located within the same organization. Refer to [Section 3.4, Funding Details](#), for detailed budget information.

iii. Project/Performance Site Location(s) Form

iv. Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov submissions only)*

4.3.2. Full Application Components for the Partnering PI

Refer to the equivalent attachment above for details specific to each of the following application components. See [Appendix 1](#) for a checklist of the full application components required for the Partnering PI.

(a) [SF424 Research & Related Application for Federal Assistance Form](#) (*Grants.gov Submissions Only*):

(b) Attachments:

- [Attachment 5: Statement of Work \(three-page limit\)](#): Upload as “SOW.pdf”. Each PI must submit an identical copy of a jointly created SOW.
- [Attachment 14: Representations](#) (*Grants.gov submissions only*): Upload as “RequiredReps.pdf”.
- [Attachment 15: Suggested Intragovernmental/Intramural Budget Form](#): Upload as “IGBudget.pdf”.

(c) [Additional Application Materials](#)

The following are additional application materials for application submission. Follow the instructions specific to the submission portal found within the GAI.

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Grants.gov



eBRAP.org

i. Research & Related Senior/Key Person Profile (Expanded)

- **Biographical Sketch**
- **Current/Pending Support**

Intragovernmental applicants must include their internally supported research and development programs.

ii. Research & Related Budget

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Partnering PI should not include budget information for the Initiating PI, or vice versa, even if they are located within the same organization. Refer to [Section 3.4, Funding Details](#), for detailed budget information.

iii. Project/Performance Site Location(s) Form

iv. Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov submissions only)*

4.4. Other Application Elements

If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, [DoD Instructions 3200.12](#) will be requested.



The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

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5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942526ARPCTA from [Grants.gov](#) or [eBRAP](#), depending on which submission portal will be used.

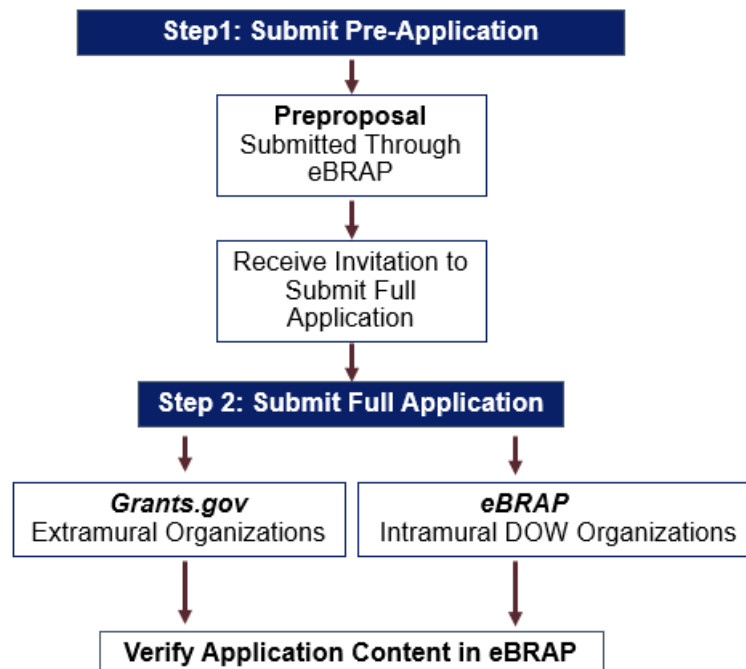
5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), [SAM.gov](#), and receive confirmation of an “Active” status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration. i

5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions. The workflow below shows which portal system to use for pre- and full application submissions, respectively.


Application Submission Workflow



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5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI through [eBRAP](#), including the submission of contact information for the Partnering PI if selecting the Early Career Investigator Option. 

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. Contact the [eBRAP Help Desk](#) if any changes need to be made.

Partnering PI Option for Early Career Investigator: After the Initiating PI confirms submission of the pre-application, the Partnering PI will be notified of the pre-application submission via an email from eBRAP. The Partnering PI must follow the instructions provided in the email to associate the partnering pre-application with their eBRAP account. If not previously registered, the Partnering PI must register in eBRAP.


Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI. Partnering PIs are urged to associate the partnering pre-application with their eBRAP account as soon as possible. If this is not completed by the full application deadline:


- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.
- The Partnering PI will not be able to view and modify their full application during the verification period in eBRAP.

When starting the pre-application, PIs should select a Mechanism Option appropriate to their pre-application:


Application Includes:	Select Mechanism Option:
Single PI	CTA – Clinical Trial Award
Partnering PI Option for Early Career Investigator	CTA-ECI – Clinical Trial Award – Early-Career Investigator

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace. 

eBRAP Submissions: Only [intramural DOW organizations](#) may submit full applications through eBRAP. 

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of the submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log in to eBRAP to review, modify and verify the full application submission. 

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The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the [application verification period](#) ends. The full application cannot be modified once the application verification period ends.

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The DHACA cannot make allowances/exceptions for submission problems encountered by the applicant.***

Submission dates and times are specified in [Section 1, Basic Information](#).

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

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6. Application Review Information

6.1. Application Compliance Review

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).

While it is allowable to propose similar research projects to different programs within the CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the [CDMRP's Directive on Research Duplication](#).

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. 

Members of the FY26 ARP Programmatic Panel must not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members **may** provide [letters](#) to confirm [PI eligibility](#) and access to laboratory space, equipment and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). **A list of the [FY26 ARP Programmatic Panel members](#) can be found on the CDMRP website.**

Additional restrictions and associated administrative responses are outlined in [Section 9.2, Administrative Actions](#).

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

To determine the merits of the pre-application and the relevance to the mission of the ARP, pre-applications will be screened based on the following criteria:

- **Research Idea:** Whether the proposed research addresses one or more of the [FY26 ARP Clinical Trial Award Areas of Interest](#) or, if not, whether justification was provided that the proposed research addresses a critical problem, question, or need in autism. How well the rationale, study design, methods used, and specific aims support the project's hypothesis or objective(s). To what degree the study population appropriately represents the autism community and the project's objective.
- **Intervention:** To what extent the intervention appears feasible, whether the potential benefits outweigh potential risks, and whether outcome measures are appropriate to the intervention and subject population.
- **Clinical Impact:** What potential impact this study will have on the outcomes of Autistic individuals, and, if applicable, their families/caregivers and/or the understanding of autism.
- **Personnel:** How the background, experience, and expertise of the personnel are appropriate to accomplish the proposed research (e.g., statistical expertise, expertise in autism and clinical trials, meet the PI eligibility requirements).

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- **Partnering PI Option for Early-Career Investigator (if applicable):** How well the Researcher Development Plan will contribute to fostering the Early-Career Investigator's development as an autism clinical trial researcher. To what degree the Initiating PI (Mentor) is positioned to mentor the Early-Career Investigator toward a successful career in autism clinical trial research.

6.2.2. Peer Review Criteria

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

- **Research Strategy and Feasibility**
 - How well the scientific rationale for the proposed clinical trial is supported by the preliminary data presented, review and analysis of the available literature and completed/ongoing studies.
 - To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention.
 - How well the specific aims/hypotheses/research question, study design, experimental methods, data collection procedures and evaluations are designed to address the clinical objective and purpose of the study.
 - How well studies are designed to achieve reproducible and rigorous results, including the endpoints/outcomes to be measured.
 - How well potential challenges and alternative strategies are discussed.
- **Intervention and Regulatory Strategy**
 - Whether there is evidence of support, indicating availability of the intervention from its source, for the duration of the proposed clinical trial (if applicable).
 - To what degree the intervention addresses the clinical need(s) described.
 - How the intervention compares with currently available interventions and/or standards of care.
 - To what degree the preclinical and/or clinical evidence supports the safety and stability (as appropriate) of the intervention.
 - How well research procedures are clearly delineated from routine clinical procedures.
 - To what degree the planned route and schedule of study intervention(s), evaluations(s) and follow-up procedures are reasonable for study participants to experience.
 - Whether plans to comply with the GMP, GLP and GCP guidelines are appropriate.
 - If applicable, whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
 - Whether the application includes documentation that the study is exempt from FDA or other international agency regulation, or that the IND or IDE application (and/or international equivalent) has been submitted to the FDA and/or relevant international Regulatory Agency, as appropriate.
 - How well the documentation provided supports the feasibility of acquiring an active IND or IDE FDA approval (and/or international equivalent) covering the proposed trial, if applicable.

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- For investigator-sponsored IND applications, whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA.
- How the regulatory strategy and development plan to support the product indication or product label change are appropriate and well described (if applicable).
- **Recruitment, Accrual, Retention**
 - To what degree the number of human subjects to be enrolled in 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 trial, 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 trial.
 - How well the application identifies possible delays (e.g., slow/low enrollment, poor retention) and presents adequate mitigation plans to resolve them.
 - To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study.
 - 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, race and/or ethnicity is appropriate for the proposed research.
- **Clinical Impact**
 - How impactful the anticipated outcomes of the proposed clinical trial would be to the target population with regard to the [FY26 ARP Clinical Trial Award Area\(s\) of Interest](#).
 - How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
 - To what degree the intervention addresses current clinical need(s) or improves upon available interventions and/or standards of care.
 - How the implementation/dissemination of the intervention and/or research outcome(s) will improve patient care and/or quality of life for the autism community.
 - If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- **Community Collaboration**
 - To what extent the background, experience and effort of the community collaborative research partner(s) are appropriate to support the proposed research study.
 - How well the community partner is integrated into the study and to what extent this input has and/or will be meaningfully incorporated into the research design, execution and dissemination of the research.
- **Statistical Plan and Data Analysis**
 - To what degree the statistical model and data analysis plan are suitable for the planned study objectives.

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- To what degree the sample size projections are adequate to ensure proper power for the study, and as applicable, any subgroup analysis.
- Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study or whether the justification for a single sex study is sufficiently strong.
- **Transition Plan**
 - To what degree the next logical steps to be taken upon successful completion of the proposed clinical trial are realistic and appropriate to bring the research outcome(s) to the next stage of clinical development/implementation/dissemination.
 - To what degree the collaborations and other resources (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources) intended to help advance the research outcome(s) are established and/or achievable.
 - For knowledge products, whether the proposed collaborations and other resources are achievable to provide continuity of development.
 - To what degree ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award are considered and planned for.
 - To what extent the plan for sharing of project data and research resources is appropriate and reasonable and includes dissemination to affected communities, study participants and/or the scientific community. If applicable, whether specific repository(ies) are named where data and research resources arising from the project will be stored.
- **Ethical Considerations**
 - Whether the population selected to participate in the trial stands to benefit from the knowledge gained.
 - 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 of seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
 - To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study.
 - If applicable, to what degree barriers to clinical trial participation have been considered and/or addressed.
- **Personnel and Communication**
 - To what degree the composition of the study team, including any external consultants or advisors (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate), 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 trial.
 - How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures, multi-institutional

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structure governing the research protocol(s) are appropriate and meet the needs of the proposed clinical trial.

The following separately scored criteria evaluate only the merits of the proposed Partnering PI Option for **Early-Career Investigator** application, if applicable. These criteria are considered independent components of the application evaluation and will be used at the programmatic review to make funding recommendations for applications submitted under the Partnering PI Option for Early-Career Investigator:

- **Early-Career Investigator**

- To what extent the Partnering PI's (Early-Career Investigator's) achievements (as reflected by academic performance, awards, honors, and/or previous publications and funding) indicate potential for a successful career as an autism clinical trial researcher.
- To what extent the Early-Career Investigator's stated career goals demonstrate a strong personal commitment to pursuing an independent career in autism clinical trial research.

- **Researcher Development Plan**

- How well the application has outlined a detailed, individualized Researcher Development Plan that will effectively guide and prepare the Early-Career Investigator for a career in autism clinical trial research.
- To what degree the Initiating PI's (Mentor's) experience in autism clinical trial research and mentoring, as demonstrated by a record of active funding, recent publications, and successful mentorship, positions them to mentor the Early-Career Investigator toward a successful career in autism clinical trial research.
- To what extent the scientific environment is appropriate for the proposed career development activities.

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 degree the scientific environment, clinical setting and the accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).
- Whether there is evidence for appropriate institutional commitment from each participating institution.

- **Application Presentation**

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

6.2.3. 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:

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- Ratings and evaluations of peer reviewers
- Relevance to the priorities of the FY26 ARP, as evidenced by the following:
 - Adherence to the intent of the funding opportunity
 - Program portfolio balance
 - Relative clinical impact
 - Programmatic relevance to one or more of the [FY26 ARP Clinical Trial Award Areas of Interest](#) or another important problem with respect to Autistic individuals.

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, Initiating PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in [Section 1, Basic Information About the Funding Opportunity](#). No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

6.3.2. Full Application

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 subject to review and approval by a designated official. ***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 6.2.3, Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found on the [CDMRP website](#).

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.

6.4. Risk, 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 the SAM.

An applicant organization may review the 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

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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.

In accordance with National Security Presidential Memorandum-33 and all associated laws, all fundamental research funded by the DOW must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the [DOD Component Decision Matrix](#) must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

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7. Federal Award Notices

For each compliant full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. 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 application receipt and review process for the ARP 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. After all awards are made, the CDMRP includes individual award information in a searchable [database](#).

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 DHACA 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).***

Intragovernmental 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 DOW 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 DOW 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.

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8. Post-Award Requirements


8.1. 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.

The GAI contain information regarding [administrative requirements](#) and [national policy requirements](#).

Refer to full text of the latest [DoD R&D Terms and Conditions](#) and the [DHACA Terms and Conditions](#) for further information.

If there are delinquencies in technical reporting requirements for any existing DHA or U.S. Army Medical Research and Development Command awards at the applicant organization, DHACA will not issue any new awards to the applicant organization until all delinquent reports have been submitted.

Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Additionally, the CDMRP requires all funded clinical trials to register and submit study results on [ClinicalTrials.gov](#). 

Applications recommended for funding that involve animals, human data, human specimens, human subjects or human cadavers must be reviewed for compliance with federal animal and/or human subjects protection requirements and must be approved by the DHA R&D Office of Research and Regulatory Compliance (ORRC), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), IRB or Ethics Committee (EC) review. 

8.2. Reporting

Quarterly and annual technical progress reports, as well as a final technical progress report, will be required. Technical progress reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

Enrollment reporting on the basis of sex, race and ethnicity will be required with each annual and final progress report. The [PHS Inclusion Enrollment Report](#) is available in eBRAP.

Award Expiration Transition Plan: An [Award Expiration Transition Plan](#), using the template available on eBRAP, must be submitted with the final progress report.

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

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 the SAM about certain civil, criminal and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with their 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](#).

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8.3. Additional Requirements

Unless otherwise restricted, changes in the PI or Partnering PI 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.

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

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9. Other Information

9.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name and the program announcement version code CD26_01Td.

9.2. Administrative Actions

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

9.2.1. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.

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

- The Project Narrative is missing.
- The Budget is missing.
- The Intervention ([Attachment 6](#)) missing
- The Study Population Recruitment and Safety Plan ([Attachment 7](#)) is missing.
- The Regulatory Strategy ([Attachment 8](#)) is missing.
- The Study Personnel and Organization ([Attachment 9](#)) is missing.
- Submission of an application for which a letter of invitation was not issued,

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to reviewing all documents.
- Documents not requested will be removed.

9.2.3. Withdrawal

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

- A member of the FY26 ARP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- The application includes the name(s) of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY26, the identities of the peer review contractor and the programmatic review contractor may be found on the [CDMRP website](#).
- 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.

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- The application from an extramural organization, including non-DOW federal agencies, is received through eBRAP.
- The federal government recipient organization (including an intramural DOW organization): (a) cannot accept and execute the entirety of the requested budget in FY26 funds; and/or (b) cannot coordinate the use of contractual, assistance or other appropriate agreements to provide funds to collaborators.
- The application fails to conform to this program announcement description.
- The application includes URLs, with the exception of links in the References Cited and Publication and/or Patent sections.
- The application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The same research project is submitted to different funding opportunities within the same program and fiscal year.
- An investigator may be named as a PI on a single application to this program announcement. If an investigator is named multiple times as a PI, only the first application(s) received will be accepted; additional applications will be administratively withdrawn.
- The proposed research is not a clinical trial.
- The proposed project includes preclinical research.
- The PI does not meet the [eligibility criteria](#).
- The Early-Career Investigator does not meet the eligibility criteria.
- An IND or IDE application and/or international equivalent has not been submitted prior to the application submission deadline for a study regulated by a relevant Regulatory Agency.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.
- The invited application proposes a different research project than that described in the pre-application.

9.2.4. 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 DHACA Grants Officer for a determination of the final disposition of the application.

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Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded	
	PI/Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance <i>(Grants.gov submissions only)</i>	<input type="checkbox"/>	<input type="checkbox"/>
Summary (Tab 1) and Application Contacts (Tab 2) <i>(eBRAP submissions only)</i>	<input type="checkbox"/>	<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"/>	<input type="checkbox"/>
Intervention – Attachment 6, upload as “Intervention.pdf”	<input type="checkbox"/>	
Study Population Recruitment and Safety Plan – Attachment 7, upload as “StudyPopPlan.pdf”	<input type="checkbox"/>	
Regulatory Strategy – Attachment 8, upload as “Regulatory.pdf”	<input type="checkbox"/>	
Study Personnel and Organization – Attachment 9, upload as “Personnel.pdf”		
Post-Award Transition Plan – Attachment 10, upload as “Transition.pdf”	<input type="checkbox"/>	
Clinical Impact Statement – Attachment 11, upload as “Impact.pdf”	<input type="checkbox"/>	
Community Collaboration Plan – Attachment 12, upload as “Collaboration.pdf”	<input type="checkbox"/>	
National Institute of Mental Health Data Archive (NDA) Submission Plan – Attachment 13, upload as “NDA.pdf”	<input type="checkbox"/>	
Representations <i>(Grants.gov submissions only)</i> – Attachment 14, upload as “RequiredReps.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Suggested Intragovernmental/Intramural Budget Form <i>(if applicable)</i> – Attachment 15, upload as “IGBudget.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
<u>Additional Application Materials</u>		
Research & Related Senior/Key Person Profile (Expanded)	<input type="checkbox"/>	<input type="checkbox"/>
Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>

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Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Research & Related Budget	<input type="checkbox"/>	<input type="checkbox"/>
Project/Performance Site Location(s)	<input type="checkbox"/>	<input type="checkbox"/>
Research & Related Subaward Budget Attachment(s) (<i>if applicable</i>)	<input type="checkbox"/>	<input type="checkbox"/>

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Appendix 2. Acronym List

ARP	Autism Research Program
ARRIVE	Animal Research: Reporting of In Vivo Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
CTA	Clinical Trial Award
DHA	Defense Health Agency
DHA R&D	Defense Health Agency Research and Development
DHA R&D-MRDC	Defense Health Agency Research and Development Medical Research and Development Command
DHACA	Defense Health Agency Contracting Activity
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DOW	U.S. Department of War
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GAI	General Application Instructions
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HIPAA	Health Insurance Portability and Accountability Act
IACUC	Institutional Animal Care and Use
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NDA	National Institute of Mental Health Data Archive
NIH	National Institutes of Health
ORRC	Office of Research and Regulatory Compliance

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PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
R&D	Research and Development
RPPR	Research Performance Progress Report
SAM	System for Award Management
SF424 R&R	Standard Form 424 (Application for Federal Assistance, Research & Related)
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SOW	Statement of Work
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs