Program Announcement for the Defense Health Agency

Autism Research Program
Career Development Award

Funding Opportunity Number: HT942526ARPCDA

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.

Content

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).

1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2026 (FY26) Autism Research Program (ARP) Career Development Award supports early-career, independent investigators and/or the transition of established investigators from other research fields to conduct innovative, high-impact ideas or early-phase, proof-of-principle clinical trials with the potential to have a major impact on autism.

Distinctive Features: ***Applications are strongly encouraged to address one of the FY26 ARP Career Development Award Areas of Interest*** or provide justification that the proposed research addresses a critical problem, question, or need in autism.

FY26 Career Development Award submissions with a pilot clinical trial component are required to include community collaborations to optimize research impact. Applications are expected to name at least one community partner (e.g., an Autistic individual or caregiver, representatives of community-based organizations) who will provide advice and consultation throughout the planning and implementation of the research project.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $1.5 million (M) to fund approximately two Career Development Award applications with total cost caps of $0.75M per award. The maximum period of performance is 3 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: HT942526ARPCDA

Assistance Listing Number: 12.420

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 PI on the application, regardless of ethnicity, nationality or citizenship status.

- The investigator named by the organization as the PI on the application may select one of the following eligibility categories. These eligibility criteria are applicable as of the application submission deadline:
    - An independent investigator at or below the level of Assistant Professor or equivalent; or
    - An established independent investigator in an area other than autism at or above the level of Assistant Professor seeking to transition to a career in autism, thereby bringing their expertise to the field.
- In addition, the PI must:
    - Not have received a Career Development Award (or equivalent) previously from any program within the CDMRP or any other federal funding agency.
    - Not have received more than $250,000 in total direct costs for previous or concurrent autism research as a PI of one or more federally or privately funded, non-mentored, peer-reviewed grants.
    - Must hold a Ph.D., M.D., M.D./Ph.D., or equivalent at time of pre-application submission.
    - ***Not be a graduate student, postdoctoral fellow, or other "mentored" researcher.***

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 GAI for additional recipient qualification requirements.

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 $164.4M. 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 Career Development Award mechanism was first offered in FY21. Since then, 82 Career Development Award applications were received, and 16 were recommended for funding.

3.2. Intent of the Career Development Award

The Career Development Award (CDA) supports early-career, independent investigators and/or the transition of established investigators from other research fields to conduct innovative, high-impact ideas or early-phase, proof-of-principle clinical trials with the potential to have a major impact on autism.

3.2.1. Areas of Interest for the CDA

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 Career Development Award areas of interest:

- Assessment of novel therapeutics using valid preclinical models
- 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
- 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)
- Environmental risk factors
- Factors impacting quality of life for current and former military Families
- Factors promoting success in key transitions of Autistic individuals over their lifespan

- Improve diagnosis and access to services across the lifespan
- Interventions to support Autistic individuals and their families, including key transitions into adulthood and across their lifespan
- Long-term treatment outcomes from previous clinical trials for the core symptoms of autism or to alleviate co-occurring conditions
- Mechanistic studies focused on:
    - Heterogeneous clinical expression of autism
    - Underlying conditions co-occurring with autism (e.g., pain, sleep disturbances, gastrointestinal issues, inflammation, aggression, depression, anxiety, attention deficit and seizures)
    - Sex differences in autism (i.e., prevalence, biological mechanisms, phenotypic expression, core and comorbid syndrome expression and outcomes, developmental trajectories, diagnosis and treatment response)
- 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 CDA

- **Impact:** The proposed research is expected to make an important and original contribution to advancing the understanding of autism and ultimately lead to improved outcomes for Autistic individuals and their families/caregivers. The project's impact on both autism research and autism care should be clearly articulated. A statistical plan is an important aspect of the FY26 ARP Career Development Award to demonstrate the significance of any research outcomes or findings.
- **Preliminary Data:** Although the proposed research must have direct relevance to autism, the required preliminary data, which may include unpublished results from the laboratory of the PI(s), research team, or collaborators named on the application, may be from outside the autism research field. Research should also be based on a sound scientific rationale that is established through logical reasoning and critical review and analysis of the literature.
- **Personnel:** The FY26 ARP seeks applications from investigators in the early stages of their autism career. The FY26 ARP Career Development Award is designed to support the continued development of promising independent investigators that are early in their faculty

appointments **or** the transition of established investigators from other research fields into a career in the field of autism research. Applicants are strongly encouraged to strengthen their applications through collaboration with investigators experienced in autism research and/or possessing other relevant expertise as demonstrated by a record of funding and publications.

3.2.3. Other Important Considerations for the CDA

In accordance with the National Defense Authorization Act for Fiscal Year 2026, Section 732, CDMRP does not support the conduct of painful research (U.S. Department of Agriculture pain category D or E) involving domestic cats or dogs, except for studies relating to military or service animals.

Clinical trials are allowed within this funding opportunity.

An informational resource for preparing an application, the Human Subject Research Resource, is available on the CDMRP website.

FY26 Career Development Award submissions with a pilot clinical trial component 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 Career Development Award are expected to name at least one community partner (e.g., an 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 11, Community Collaboration Plan).

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 **3** years.

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$750,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted

in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

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

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

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the ARP Career Development Award.
- 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.

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

Pre-application submissions must include the following components.

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

- **Preproposal Narrative (two-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:

  - **Principal Investigator:** Describe the PI's potential for a career at the forefront of autism research, including qualifications and achievements that make the PI an ideal candidate for this award. Describe the PI's career goals as an autism researcher and how the proposed research experience will advance their career.
  - **Research Idea:** State the hypothesis to be tested or the objective(s) to be reached. State the FY26 ARP Career Development Award Areas of Interest that will be addressed. If the proposed project does not address one of the Career Development Award areas of interest, provide justification that the proposed research addresses a critical problem, question, or need in autism. Detail the ideas and reasoning on which the proposed project is based. Concisely state the specific aims and provide a brief overview of the study design and details of the methods to be used. If the proposed research includes a clinical trial, briefly state the clinical intervention, subject population(s), and phase of the clinical trial.
  - **Impact:** Describe the potential impact, both short- and long-term, of this study on the outcomes of Autistic individuals, their families/caregivers, and/or the understanding of autism.
- **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.

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 (page limits vary, as shown below): Upload as "ProjectNarrative.pdf".**

  Describe the proposed project in detail using the outline below.

  - **Page Limit:** Page limits vary:
    - **Projects without a clinical trial:** Eight-page limit
    - **Projects with a clinical trial component:** 15-page limit

  Describe the proposed project in detail using *one* of the two outlines below, depending on whether or not a clinical trial is proposed. ***The inclusion of preliminary data relevant to the proposed project, but not necessarily derived from autism studies, is required.***

  Outline for projects without a clinical trial:

  - **Background:** Present the scientific rationale behind the proposed research; include relevant literature citations. Describe and show the preliminary data to justify the rationale for the proposed project.
  - **Hypothesis(es) and/or Objective(s):** State the hypotheses/study questions to be tested and overall objective(s) to be reached. Describe how the project addresses one or more of the FY26 ARP Career Development Award Areas of Interest or a critical problem or question in autism.
  - **Specific Aims:** Concisely explain the project's specific aims supported by this application. If this application is part of a larger study, present only tasks that this award would fund.

- **Research Strategy:** Describe the experimental design, methods, and analyses, with appropriate controls, in sufficient detail for assessment. Address potential limitations and present alternative methods and approaches. If animal studies are proposed, the applicant is required to submit an Animal Research Plan (Attachment 10). If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Where relevant, describe the availability of and access to tissue, data, or human subjects.
- **Statistical Plan:** Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis. Describe in detail how the statistical plan is appropriate for the experimental methodology being used. ***If applicable***, describe how the human subject population is appropriate for the study and provide assurance that there is clear access to the designated population. Inclusion of a biostatistician in the study team is encouraged.
- **Principal Investigator:** Describe the PI's potential for a career at the forefront of autism research, including qualifications and achievements that make the PI an ideal candidate for this award. Describe the PI's plan for continued development as an autism researcher and/or clinician (early-stage investigator) and/or the transition into a career in the field of autism research (established investigator) and how the proposed research experience will advance their career. Discuss the appropriateness of the level of effort of the PI for successful conduct of the proposed research.

Outline for projects with a clinical trial component:

Note: The Project Narrative is NOT the formal clinical trial protocol. Instead, all elements of the proposed clinical trial necessary for peer review must be described as indicated below.

- **Background:** Present the scientific rationale behind the proposed research and include relevant literature citations. Describe and show the preliminary data and/or laboratory and/or preclinical evidence to justify the rationale for the proposed project.
- **Hypothesis(es) and/or Objective(s):** State the hypotheses/study questions to be tested and overall objective(s) to be reached. Describe how the project addresses one or more of the FY26 ARP Career Development Award Areas of Interest or another critical problem or question in autism.
- **Specific Aims:** Concisely explain the project's specific aims. If this application is part of a larger study, present only tasks that this award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for assessment. Provide a well-developed, well-integrated research strategy that supports the translational feasibility and promise of the approach. Address potential problems and present alternatives.
- **Clinical Strategy:** Describe the following under separate subheadings:
  - ***Type of clinical trial:*** Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Note whether the intervention is already in use.
  - ***Challenges and alternative strategies:*** Describe potential challenges and alternative strategies where appropriate.

- ***Scope of the trial:*** Outline the scope of the trial to be performed and the intervention to be tested.
- ***Study variables:*** Define the study variables; outline why they were chosen; and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
- ***Access to study population, recruitment plans, and inclusion/exclusion criteria:*** Indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria. Describe how the human subject population is appropriate for the study and whether there is clear access to the designated population. Specify the number of human subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site.
- ***Consent:*** Describe the informed consent process, including safeguards for vulnerable populations. If minors or other populations that cannot provide informed 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. 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 Institutional Review Board (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 participants enrolled and others that may benefit. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks are reasonable in relation to the anticipated benefits.
- ***Data Privacy and Reporting Plan:*** Explain the measures taken to protect the privacy of human subjects and maintain the confidentiality of study data. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable.

– **Statistical Plan:** Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis. Describe how the statistical plan is appropriate for the methodology being used. Describe how the human subject population is appropriate for the study and provide assurance that there is clear access to the designated population. Inclusion of a biostatistician in the study team is encouraged.

- **Principal Investigator:** Describe the PI's potential for a career at the forefront of autism research, including qualifications and achievements that make the PI an ideal candidate for this award. Describe the PI's plan for continued development as an autism researcher and/or clinician (early-stage investigator) and/or the transition into a career in the field of autism research (established investigator) and how the proposed research experience will advance their career. Discuss the appropriateness of the level of effort of the PI for successful conduct of the proposed research.

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.

- **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.
- **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. 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.

- **Sex as a Biological Variable (SABV) Strategy (two-page limit is recommended):** Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.
- **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **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 research participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed study 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.

- **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 scientific rationale behind the proposed research project.
  - **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached.
  - **Specific Aims:** State the specific aims of the study.
  - **Study Design:** Describe the study design, including appropriate controls.
  - **Impact:** Summarize how the proposed project is relevant to and will have an impact on the outcomes of Autistic individuals, their families/caregivers, and/or the

understanding of autism. Describe the impact on the specified population, if applicable.

- **Career Development:** Describe how the award will provide the PI with the opportunity to effectively advance an independent career in autism research.
- **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.***

  - State the FY26 ARP Career Development Award Area(s) of Interest or another critical problem, question, or need in autism addressed by the project.
  - Describe the ultimate applicability of the research.
    - Who will it help and how will it help them?
    - What are the potential clinical applications, benefits, and risks? If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field.
    - What is the projected time anticipated to achieve a clinically relevant outcome?
    - What are the likely contributions of this study to advancing the field of autism research and ultimately leading to improved outcomes for Autistic individuals and the well-being of their families/caregivers?
  - How is the project relevant to military Service Members, Veterans and their Families?
  - Describe the PI's career goals in autism research.
    - How will the award advance the PI's career in autism research?
    - How do the research and career development plan support autism research in attaining these goals?

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the Suggested SOW Format.

  For guidance on preparing the SOW, refer to either the Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work or Example: Assembling a Generic Statement of Work, whichever is most appropriate for the proposed effort. Include milestones for data or research resource(s) sharing.

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** Describe how the proposed research is relevant to autism now. Detail the anticipated outcome(s)/product(s) and/or improved understanding of autism that will be directly attributed to the results of the proposed research project (near-term impact). Explain the anticipated long-term impact from the proposed research project, including details on how this work will have a real-world impact on the autism community. If applicable, compare the anticipated outcomes from the proposed project to currently available autism information, products or treatments. If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.

If a clinical trial component is proposed, explain how the aims of the project will have a significant clinical impact on Autistic individuals. Describe how the long-term benefits for implementation of the intervention may impact patient care and/or quality of life. Describe how well the project will translate promising, well-founded research findings into a larger clinical trial for a novel autism intervention.

- **Attachment 7: Eligibility Statement (one-page limit): Upload as "Eligibility.pdf".** Provide a letter, signed by the PI and the department chair, dean, or equivalent official, verifying that the eligibility requirements will be met by the application submission deadline. The letter should verify that the PI holds a Ph.D., M.D., M.D./Ph.D., or equivalent; that the PI is an independent investigator at or below the level of Assistant Professor, Instructor (or equivalent) or an established independent investigator in an area other than autism who is at or above the level of Assistant Professor and is seeking to transition to a career in autism, thereby bringing their expertise to the field; that the PI has not received more than $300,000 in total direct costs for previous or concurrent autism research as a PI of one or more federally or privately funded, non-mentored peer-reviewed grants; and that the PI has not received a Career Development Award previously from any program within the CDMRP (refer to Section 2.1.2, Principal Investigator for eligibility information).

  Note: Graduate students, postdoctoral fellows, or other "mentored" researchers are not eligible for the FY26 Career Development Award.

- **Attachment 8: Research Outcomes Plan (one-page limit): Upload as "Outcomes.pdf".** Describe the anticipated research outcomes, including knowledge products, clinical products for development, etc. Describe the methods and strategies proposed to move the anticipated research outcomes to the next phase of development or clinical application after successful completion of the project. Detail the funding strategy to transition to the next level of investigation, development and/or commercialization (e.g., partners, applications for internal/external funding opportunities).

- **Attachment 9: Inclusion Enrollment Report *(only applicable and required for applications proposing clinical research studies)*: Upload as "Enrollment.pdf".** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the "Public Health Service (PHS) Inclusion Enrollment Report," a three-page fillable PDF form that can be downloaded from eBRAP. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race (typically classified as exempt from Institutional Review Board (IRB) review are exempt from this requirement.

- **Attachment 10: Animal Research Plan (only applicable and required for applications proposing animal studies; three-page limit): Upload as "AnimalResPlan.pdf".**

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

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

- **Attachment 11: Community Collaboration Plan (required if proposing a clinical trial component): 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 as part of 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 12: Regulatory Strategy (applicable only if proposing a clinical trial; no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".**

  Describe the regulatory strategy using the following outline and provide supporting documentation as applicable.
  - State the product/intervention name.

For products/interventions that do not require regulation by the FDA or an international Regulatory Agency:

- **Explain why the product/intervention is exempt from oversight. Provide confirmation that the trial does not require regulation by the FDA/Regulatory Agency in writing from the IRB of record or the FDA/Regulatory Agency**. If the clinical trial will be conducted at international sites, provide equivalent information relevant to the regulatory requirements of the host country(ies). No further information for this attachment is required.

For products/interventions that require regulation by the FDA or an international Regulatory Agency:

- State whether the product is FDA-approved, -licensed, or -cleared and marketed in the U.S.
- If the product/intervention ***has*** already received FDA approval:
  - Provide a copy of the acceptance letter from the FDA.
  - If the product is marketed in the U.S., state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).
- If the product/intervention ***has not*** already received FDA approval:
  - State the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic or combination product. Indicate whether the FDA has confirmed the proposed classification.
  - Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.
  - If an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application is required to initiate the proposed research project, it must be submitted to the FDA prior to the FY26 ARP Career Development Award application submission deadline. The government reserves the right to withhold or withdraw funding if an IND or IDE application is necessary but has not been submitted to the FDA by the application submission deadline or if the documented status of the IND or IDE application has not been obtained within 9 months of the award date.
  - 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).

If a device is to be used in the proposed clinical trial, indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for the conduct of the clinical trial.

- **Attachment 13: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.

- **Attachment 14: 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.

(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

iii. Project/Performance Site Location(s)

iv. Research & Related Subaward Budget Attachment(s) *(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.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942526ARPCDA from Grants.gov or eBRAP, depending on which submission portal will be used.

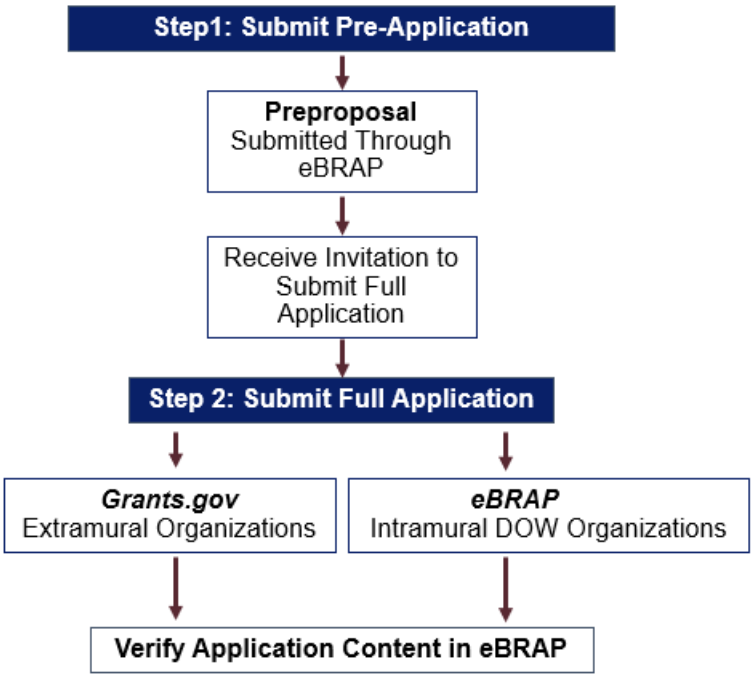
5.2. Unique Entity Identifier and System for Award Management

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.

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



5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI through eBRAP.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify and verify the application in eBRAP. Contact the eBRAP Help Desk if any changes need to be made.

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

Application Includes:	Select Option:
CDA	CDA – Career Development Award
CDA with Pilot Clinical Trial	CDA – Career Development Award – Pilot Clinical Trial

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. ***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.

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:

- **Principal Investigator:** How well the PI's potential for a career at the forefront of autism research is supported by their qualifications and achievements. The degree to which the PI's career goals as an autism researcher and the proposed research experience will advance their career.
- **Research Idea:**
    - Whether the proposed research addresses one or more of the FY26 ARP Career Development 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
    - To what extent the research can be accomplished with the defined subject population, if applicable.

- **Impact:** What potential both short- and long-term impact this study will have on the outcomes of Autistic individuals, their families/caregivers and/or the understanding of autism.

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***:***

For applications without a clinical trial:

- **Scientific Merit**
  - To what extent a clear hypothesis is stated and supported through scientific rationale, preliminary data, and referenced literature.
  - How well the hypothesis or objectives, specific aims and experimental design are developed.
  - How well the study is designed to achieve the research objectives, including, if applicable, the development and use of animal model(s), and to what extent the chosen animal and endpoints/outcome measures are justified.
  - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
  - If applicable, to what extent the human subject population is appropriate for the study and whether there is clear access to the designated population.
  - If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
  - How well the application acknowledges potential problems and addresses alternative approaches.
  - To what degree the statistical plan is appropriate for the experimental methodology being used.
  - Whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed, if applicable.
- **Impact**
  - To what degree the proposed project is relevant to autism.
  - To what extent the anticipated near-term outcome(s)/product(s) of the project will impact Autistic individuals and their families/caregivers and/or improve understanding of autism.
  - To what degree the anticipated long-term impact from the proposed research project will have a real-world impact on the autism community.
  - How well the proposed study addresses one or more of the FY26 ARP Career Development Award Areas of Interest or justifies that the proposed research addresses a critical problem, question, or need in autism.
  - How the anticipated outcomes from the proposed project compare to currently available autism information, products or treatments, if applicable.

- **Research Outcomes Plan**
  - Whether the application described the anticipated research outcomes, including knowledge products, clinical products for development, etc.
  - How well the application demonstrated methods and strategies to move the anticipated research outcomes to the next phase of development or clinical application after successful completion of the project.
  - Whether the application detailed the funding strategy to transition to the next level of investigation, development, and/or commercialization (e.g., partners, internal/external funding opportunities to be applied 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.
- **Principal Investigator and Research Team**
  - Principal Investigator
    - How well the PI's potential for a career at the forefront of autism research is supported by their qualifications and achievements.
      - For early-stage investigators, to what extent the PI has a potential for continued development in the field of autism research.
      - For established investigators, to what extent the PI will bring their expertise to the field of autism research and pursue an active line of research centered on autism.
    - The degree to which the PI's career goals as an autism researcher and/or clinician and the proposed research experience will advance their career.
    - The degree to which the PI's level of effort is appropriate for the successful conduct of the proposed research.
  - Research Team
    - To what extent the research team's background and expertise are appropriate to accomplish the proposed research.

For applications with a clinical trial component:

- **Scientific Merit**
  - How well the scientific rationale for testing the intervention/clinical research is supported by the preliminary data, critical review and analysis of the literature and/or laboratory and/or preclinical evidence.
  - How well the specific aims, hypotheses or objectives, experimental design, methods, data collection procedures and analyses are designed to clearly answer the clinical objective, including selection of an appropriate control condition(s) for comparison.
  - To what degree the statistical plan and the rationale for the statistical methodology, including sample size projections, are adequate for the study proposed.
  - Whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed, if applicable.

- **Clinical Strategy and Regulatory Strategy**
  - How well the clinical trial portion of the application is designed with appropriate study variables, controls, endpoints, and data analysis plan.
  - How well the application demonstrates access to the study population and ability to achieve recruitment goals.
  - How well the recruitment plan and inclusion/exclusion criteria will support achieving the objective.
  - Whether the strategy for the inclusion of women and minorities and the distribution of proposed enrollment are appropriate for the proposed research, including a description of the composition of the proposed study population in terms of sex, racial and ethnic group and an accompanying rationale for the selection of subjects.
  - Whether an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity is included.
  - Whether the proposed intervention is feasible and endpoints are rational.
  - How well the applicant acknowledges potential problems and addresses alternative approaches.
- **If applicable for the proposed clinical trial:**
  - For investigator-sponsored regulatory exemptions (e.g., IND/IDE application approval or other international equivalent), whether there is evidence of appropriate institutional support.
  - Whether the application includes documentation that the study is exempt from FDA or other international agency regulation or 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 application approval (and/or international equivalent) covering the proposed trial, if applicable.
- **Clinical Impact**
  - Whether the aims of the project are likely to have a significant clinical impact on Autistic individuals.
  - How the potential outcomes of the proposed study will provide/improve near-term benefits for Autistic individuals.
  - How significantly the long-term benefits for implementation of the intervention may impact patient care and/or quality of life.
  - To what extent the proposed project will ultimately improve the outcomes.
  - How well the proposed study addresses one or more of the FY26 ARP Career Development Award Areas of Interest or, if not, justifies that the proposed research addresses a critical problem, question, or need in autism.
- **Research Outcomes Plan**
  - Whether the application described the anticipated research outcomes, including knowledge products, clinical products for development, etc.

- How well the application demonstrated methods and strategies to move the anticipated research outcomes to the next phase of development or clinical application after successful completion of the project.
- Whether the application detailed the funding strategy to transition to the next level of investigation, development, and/or commercialization (e.g., partners, internal/external funding opportunities to be applied 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**
  - How well the evidence shows that the intervention is consistent with sound research design and minimizes the level of risk to human subjects, and, when appropriate, that the intervention is already in use.
  - To what degree privacy issues are appropriately considered.
  - To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
- **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.
- **Principal Investigator and Research Team**
  - Principal Investigator
    - How well the PI's potential for a career at the forefront of autism research is supported by their qualifications and achievements.
      - For early-stage investigators, to what extent the PI has a potential for continued development in the field of autism research.
      - For established investigators, to what extent the PI will bring their expertise to the field of autism research and pursue an active line of research centered on autism.
    - The degree to which the PI's career goals as an autism researcher and/or clinician and the proposed research experience will advance their career.
    - The degree to which the PI's level of effort is appropriate for the successful conduct of the proposed research.
  - Research Team
    - To what extent the research team's background and expertise are appropriate to accomplish the proposed research.
    - To what degree the qualifications and background of the community partners are relevant to their roles within the team and to the proposed research project.

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

- **Budget**
  - Whether the budget is appropriate for the proposed research.
- **Environment**
  - To what extent the scientific environment is appropriate for the proposed research project.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
  - To what extent the quality and level of institutional support are appropriate for the proposed research project.
- **Application Presentation**
  - To what extent the writing, clarity and presentation of the application components influence the review.

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:

- 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 award mechanism
  - Program portfolio balance
  - Relative impact
  - Programmatic relevance to one or more of the FY26 ARP Career Development Award areas of interest or another critical problem or question in autism

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, 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 the Code of Federal Regulations, Title 2, Part 200.1 (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 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.

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.

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.

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 IACUC, IRB or Ethics Committee (EC) review.

Funded trials are required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in the Code of Federal Regulations, Title 32, Part 219 (32 CFR 219). Funded studies are required to register the study in the NIH clinical trial registry prior to initiation of the study. Refer to the GAI, Appendix 6, Section F, for further details.

8.2. Reporting

Annual technical progress reports as well as a final technical progress report will be required. For studies conducting clinical research or a clinical trial, quarterly reports will be required. Annual and final technical progress reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

PHS Inclusion Enrollment Reporting ***(required for research proposing clinical research and/or clinical trials)***: Enrollment reporting on the basis of sex, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on 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.

8.3. Additional Requirements

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis.

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

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

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_01d.

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:

- The Preproposal Narrative is missing.

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

- The Project Narrative is missing.
- The Budget 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.
- 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 PI does not meet the eligibility criteria.
- 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.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance ***(Grants.gov submissions only)***	☐
Summary (Tab 1) and Application Contacts (Tab 2) ***(eBRAP submissions only)***	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐
Eligibility Statement – Attachment 7, upload as "Eligibility.pdf"	☐
Research Outcomes Plan – Attachment 8, upload as "Outcomes.pdf"	☐
Inclusion Enrollment Report – Attachment 9, upload as "Enrollment.pdf"	☐
Animal Research Plan – Attachment 10, upload as "AnimalResPlan.pdf"	☐
Community Collaboration Plan – Attachment 11, upload as "Collaboration.pdf"	☐
Regulatory Strategy – Attachment 12, upload as "Regulatory.pdf"	☐
Representations ***(Grants.gov submissions only)*** **– Attachment 13, upload as "RequiredReps.pdf"**	☐
Suggested Intragovernmental/Intramural Budget Form ***(if applicable)*** **– Attachment 14, upload as "IGBudget.pdf"**	☐
Additional Application Materials	
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)	☐
Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)	☐
Research & Related Budget	☐
Project/Performance Site Location(s)	☐
Research & Related Subaward Budget Attachment(s) ***(if applicable)***	☐

Appendix 2. Acronym List

ARP	Autism Research Program
ARRIVE	Animal Research: Reporting of In Vivo Experiments
CDA	Career Development Award
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
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
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
ORRC	Office of Research and Regulatory Compliance
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
R&D	Research and Development

RPPR	Research Performance Progress Report
SABV	Sex as a Biological Variable
SAM	System for Award Management
SF424 R&R	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
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