I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Autism Research Program

Career Development Award

Announcement Type: Initial

Funding Opportunity Number: HT942524ARPCDA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), May 16, 2024
- **Invitation to Submit an Application:** June 26, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, August 15, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, August 19, 2024
- **Peer Review:** October 2024
- **Programmatic Review:** December 2024

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

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Autism Research Program (ARP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the ARP in 2007 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the ARP from FY07 through FY23 totaled $149.4 million (M). The FY24 appropriation is $15M.

The ARP's vision is to improve the lives of individuals with Autism Spectrum Disorders (ASD) now and in their future, and its mission is to promote innovative research that advances the understanding of ASD and leads to improved outcomes.

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.

II.A.1. FY24 ARP Career Development Award Areas of Interest

To meet the intent of the funding opportunity the ARP ***encourages*** applications that address critical needs of the ASD community in one or more of the FY24 ARP Career Development Award Areas of Interest:

- Assessment of novel therapeutics using valid preclinical models
- ***(New for FY24)*** Community supported and participatory research interventions
- Create tools and strategies to increase the speed with which evidence-based practices are deployed in community-based settings
- Cultural, socioeconomic, and gender factors in diagnosis, treatment efficacy, delivery, and access to services
- Development of health care provider-focused training or tools to improve health care delivery for individuals with ASD across the life span and the continuum of care (i.e., primary care, urgent/emergent care, and disaster relief)
- Environmental risk factors
- ***(New for FY24)*** Factors impacting quality of life for current and former military families.
- Factors promoting success in key transitions to independence for individuals living with ASD

- ***(New for FY24)*** Gender identity and sexual health, including puberty and sexual education for autistic individuals
- Improve diagnosis and access to services across the life span
- Interventions to support ASD adults, including transition to adulthood, mid-life, and late-life needs
- Long-term treatment outcomes from previous clinical trials for ASD core symptoms or to alleviate co-occurring conditions
- Mechanisms of heterogeneous clinical expression of ASD
- Mechanisms underlying sex differences (i.e., prevalence, biological mechanisms, phenotypic expression, core and comorbid syndrome expression and outcomes, developmental trajectories, diagnosis, and treatment response)
- Mechanisms underlying conditions co-occurring with ASD (e.g., pain, sleep disturbances, gastrointestinal issues, inflammation, aggression, depression, anxiety, attention deficit, and seizures)
- Mental health issues (such as grief, masking, suicide risk, trauma, etc.) or disorders in autistic individuals
- Tests of implementation strategies to increase use of evidence-based practices
- ***(New for FY24)*** 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
- Understanding key factors to support ASD adults, including transition to adulthood
- Understanding physical health and related issues in aging autistic adults, including cardiovascular issues, joint pain, asthma, obesity, etc.

The FY24 ARP Career Development Award seeks applications from all areas of research. However, if the proposed research project does not address at least one of the FY24 ARP Career Development Award Areas of Interest, justification should be provided that the proposed research addresses a critical problem, question, or need in ASD.

II.A.2. Award History

The ARP Career Development Award mechanism was first offered in FY21. Since then, 60 Career Development Award applications have been received, and 12 have been recommended for funding.

II.B. Award Information

The FY24 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 ASD. ***Applications are strongly encouraged to address one of the FY24 ARP Career Development Award Areas of Interest*** or provide justification that the proposed research addresses a critical problem, question, or need in ASD.

This award enables such investigators to compete for funding separately from investigators with established programs of ASD research. Previous experience in ASD research is allowed, but not required. However, in FY24 Career Development Award applications that name a Principal Investigator (PI) with limited background in ASD research, the ARP strongly encourages the inclusion of collaboration with investigators who are experienced in ASD research and/or possess other relevant expertise in order to strengthen the application. PIs must meet specific eligibility criteria as described in Section II.C, Eligibility Information.

Research funded by the FY24 ARP should be responsive to the needs of people with ASD, 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.

CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

Key elements of this award are as follows:

- **Impact:** The proposed research is expected to make an important and original contribution to advancing the understanding of ASD and ultimately lead to improved outcomes for Autistic individuals and their families/caregivers. The project's impact on both ASD research and ASD care should be clearly articulated. A statistical plan is an important aspect of the FY24 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 ASD, 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 ASD 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 FY24 ARP seeks applications from investigators in the early stages of their ASD career. *The FY24 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 ASD research.* Applicants are strongly encouraged to strengthen their

applications through collaboration with investigators experienced in ASD research and/or possessing other relevant expertise as demonstrated by a record of funding and publications.

- **Rigor of Experimental Design:** All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, Nature 490:187-191 (https://www.nature.com/articles/nature11556). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies.

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

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

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

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

(2) Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of clinical trial.

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

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

The anticipated direct costs budgeted for the entire period of performance for an FY24 ARP CDA should not exceed **$550,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

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

The CDMRP expects to allot approximately $2.64M to fund approximately three Career Development Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

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

II.C.1.b. Principal Investigator

- The investigator named by the organization as the PI on the application may select one of the following eligibility categories. These eligibility criteria pertain 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 ASD at or above the level of Assistant Professor seeking to transition to a career in ASD 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.

- Not have received more than $300,000 in total direct costs for previous or concurrent ASD 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.***

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

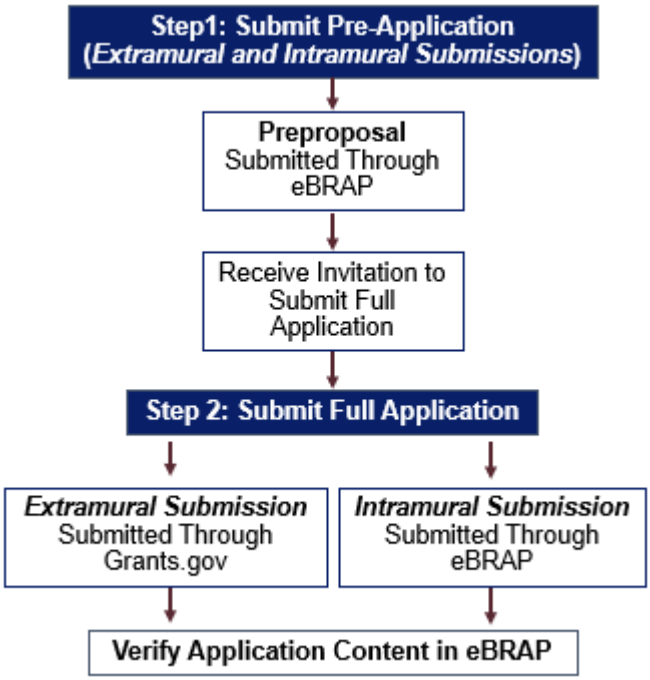
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the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

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

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

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

Application Submission Workflow



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions.) Download application package components for HT942524ARPCDA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524ARPCDA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

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

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

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

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

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

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

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

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/).

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

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

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

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

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

Note: Upload documents as individual PDF files unless otherwise noted.

- **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 ASD research, including qualifications and achievements that make the PI an ideal candidate for this award. Describe the PI's career goals as an ASD 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 FY24 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 ASD. Detail the ideas and reasoning on which the proposed project is based. Concisely state the specific aims, 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 ASD.

- **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 (five-page limit per individual):** ***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.

II.D.2.a.ii. Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program (DHP) and 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 ASD research is supported by their qualifications and achievements. The degree to which the PI's career goals as an ASD researcher and the proposed research experience will advance their career.

- **Research Idea:** Whether the proposed research addresses one or more of the FY24 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 ASD. How well the rationale, study design, methods used and specific aims support the project's hypothesis or objective(s). To what extent the research can be accomplished with the defined subject population, if applicable.

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

II.D.2.a.iii. Notification of Pre-Application Screening Results

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 I, Overview of 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.

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

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

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

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

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit

through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

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

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

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

(b) Attachments:

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

- **Attachment 1: Project Narrative (page limits vary, as shown below): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

  Describe the proposed project in detail using the outline below.

  - **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 ASD 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 FY24 ARP Career Development Award Areas of Interest or a critical problem or question in ASD.

- **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. The inclusion of a biostatistician in the study team is encouraged.

- **Enrollment Table (if applicable):** Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The Public Health Service (PHS) Inclusion Enrollment Report format is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm

- **Principal Investigator:** Describe the PI's potential for a career at the forefront of ASD 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 ASD researcher and/or clinician (early-stage investigator) and/or the transition into a career in the field of ASD 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 <u>with</u> 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 FY24 ARP Career Development Award Areas of Interest or another critical problem or question in ASD.

- **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.

  - ***Women and minorities in the study:*** Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research.

    - Describe the strategy for the inclusion of women and minorities in the clinical trial appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects.

Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

- ❖ Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The PHS Inclusion Enrollment Report format is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- ▪ ***Consent:*** Describe the informed consent process, including safeguards for vulnerable populations.

- ▪ ***Data Management Plan:*** Describe the Data Management Plan. Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data.

- ▪ ***Reporting:*** 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. The inclusion of a biostatistician in the study team is encouraged.

– **Principal Investigator:** Describe the PI's potential for a career at the forefront of ASD 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 ASD researcher and/or clinician (early-stage investigator) and/or the transition into a career in the field of ASD 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.

- ○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

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

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

- **Letters of Collaboration *(if applicable)*:** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

- **Commercial Entity Letters of Commitment *(if applicable)*:** 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 Property:** Information can be found in the 2 CFR 200.315, "Intangible Property."

    - **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations.

    - **Commercialization Strategy *(if applicable)*:** Describe the commercialization plan. The plan should include intellectual property, market size, financial

analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about CDMRP's expectations for making data and research resources publicly available.

- **Data Management Plan (2-page limit is recommended); projects without a clinical trial:** Describe the Data Management Plan in accordance with Section 3.c. Enclosure 3, DoD Instructions 3200.12. ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

  - **Research:**

    - Background: Present the ideas and reasoning behind the proposed project. Identify the FY24 ARP Career Development Award Area(s) of Interest or provide justification that the proposed research addresses another critical problem, question, or need in ASD that will be addressed by the proposed research project.

    - Hypothesis/Objective(s): State the hypothesis to be tested and/or objective(s) to be reached. Provide evidence or rationale that supports the objective(s)/hypothesis(es).

    - 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 ASD. 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 ASD research.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

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

  - Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without a background in science or medicine. State the FY24 ARP Career Development Award Area(s) of Interest or another critical problem, question, or need in ASD 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 ASD research and ultimately lead 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 ASD research.
  - How will the award advance the PI's career in ASD research?
  - How do the research and career development plan support the PI in attaining these goals?

- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

  For the Career Development Award, 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 example is most appropriate for the proposed effort, for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** Describe how the proposed research is relevant to ASD now. Detail the anticipated outcome(s)/product(s) and/or improved understanding of ASD 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 how this work may ultimately benefit the ASD community, Autistic individuals and their quality of life, and/or the well-being of their families/caregivers. Compare the anticipated outcomes from the proposed project to currently available ASD information, products or treatments, if applicable

  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 ASD intervention.

- **Attachment 7: Innovation Statement (one-page limit): Upload as "Innovation.pdf".** Summarize how the proposed research is innovative. State how the research challenges existing paradigms or provides new paradigms, technologies, evidence-based diagnoses, and/or applications for ASD. Investigating the next logical step or an incremental advancement on published data is not considered innovative.

- **Attachment 8: 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, 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 ASD at or above the level of Assistant Professor seeking to transition to a career in ASD 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 ASD 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 II.C.1.b, Principal Investigator, for eligibility information).

Note: Graduate students, postdoctoral fellows, or other "mentored" researchers are not eligible for the FY24 CDA.

- **Attachment 9: 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 10: Animal Research Plan (three-page limit): Upload as "AnimalResPlan.pdf".** ***(Attachment 10 is only applicable and required for applications proposing animal studies.)***

  If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at https://arriveguidelines.org/arrive-guidelines. 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: 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 FY24 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 documented status of the IND or IDE 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 12: Representations *(Extramural Submissions Only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.

- **Attachment 13: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".

- **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

- **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".

- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.

- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e) Budget Justification Instructions.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.

- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 13.

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

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

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

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

II.D.4. Submission Dates and Times

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

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

II.D.5. Funding Restrictions

The maximum period of performance is **3** years.

The application's direct costs budgeted for the entire period of performance should not exceed **$550,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

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

For this award mechanism, 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.

Must not be requested for:

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

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

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 applicant 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 ASD.
    - To what extent the anticipated near-term outcome(s)/product(s) of the project will impact Autistic individuals, their families/caregivers, and/or improve understanding of ASD.

- To what degree the anticipated long-term outcomes from this research project may impact the ASD community, Autistic individuals and the well-being of their families/caregivers.

- How well the proposed study addresses one or more of the FY24 ARP Career Development Award Areas of Interest or justifies that the proposed research addresses a critical problem, question, or need in ASD.

- How the anticipated outcomes from the proposed project compare to currently available ASD information, products, or treatments if applicable.

- **Innovation**

  - To what extent the proposed research is innovative and will challenge existing paradigms or provide new paradigms, technologies, evidence-based diagnoses, and/or applications for ASD.

  - To what degree the proposed research represents more than a logical extension and/or incremental advance upon published data.

- **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).

- **Principal Investigator and Research Team**

  - **Principal Investigator**

    - How well the PI's potential for a career at the forefront of ASD 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 ASD research.

      - For established investigators, to what extent the PI will bring their expertise to the field of ASD research and pursue an active line of research centered on autism.

    - The degree to which the PI's career goals as an ASD 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, expertise and level of effort are appropriate to accomplish the proposed research.

For applications <u>with</u> 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/gender, 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/gender, race, and ethnicity is included.

  - For phase 3 clinical trials, whether the application describes plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity that are appropriate for the scientific goals of the study.

- 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 short-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 FY24 ARP Career Development Award Areas of Interest or, if not, justifies that the proposed research addresses a critical problem, question, or need in ASD.
- **Innovation**
  - To what extent the proposed research will challenge existing paradigms or provide new paradigms, technologies, evidence-based diagnoses, and/or applications for ASD.
  - To what degree the proposed research represents more than a logical extension and/or incremental advance upon published data.
- **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).

- **Ethical Considerations**

  - How well the evidence shows that the intervention is consistent with sound research design, 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.

- **Principal Investigator and Research Team**

  - Principal Investigator

    – How well the PI's potential for a career at the forefront of ASD 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 ASD research.

      ▪ For established investigators, to what extent the PI will bring their expertise to the field of ASD research and pursue an active line of research centered on autism.

    – The degree to which the PI's career goals as an ASD 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, expertise and level of effort are appropriate to accomplish the proposed research.

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

- **Personnel**

  - How appropriate the levels of effort are for successful conduct of the proposed work.

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

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the DHP and FY24 ARP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Program portfolio balance
    - Relative impact and innovation
    - Programmatic relevance to one or more of the FY24ARP Career Development Award Areas of Interest or another critical problem or question in ASD

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various***

factors as described in Section II.E.1.b, Programmatic Review. Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess.

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

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the 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.

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

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. No commitment on the part of the government should be inferred from discussions with any other individual. ***The award document signed by the Grants Officer is the official authorizing document (i.e., assistance agreement).***

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

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

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

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

II.F.2. PI Changes and Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

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

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

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

II.F.3. Administrative and National Policy Requirements

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

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

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

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

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

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 (32 CFR 219). Funded studies are required to register the study in the National Institutes of Health clinical trial registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

II.F.4. Reporting

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

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

Inclusion Enrollment Reporting: ***(only required for clinical research studies and pilot clinical trials)*:** Enrollment reporting on the basis of sex/gender, race, and/or ethnicity using the PHS Inclusion Enrollment Report will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@grants.gov

II.H. Other Information

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

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

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Preproposal Narrative is missing.

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

- Submission of an application for which a letter of invitation was not issued.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

- An FY24 ARP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation. ***A list of the FY24 ARP Programmatic Panel members can be found at https://cdmrp.health.mil/arp/panels/panels24***.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The PI does not meet the eligibility criteria.
- The invited application proposes a different research project than that described in the pre-application.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
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"	☐
Innovation Statement – Attachment 7, upload as "Innovation.pdf"	☐
Eligibility Statement – Attachment 8, upload as "Eligibility.pdf"	☐
Research Outcomes Plan – Attachment 9, upload as "Outcomes.pdf"	☐
Animal Research Plan *(if applicable)* – Attachment 10, upload as "AnimalResPlan.pdf"	☐
Regulatory Strategy *(if applicable)* – Attachment 11, upload as "Regulatory.pdf"	☐
Representations *(Extramural submissions only)* – Attachment 12, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 13, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐
Budget *(Intramural submissions only)* Include budget justification	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐

APPENDIX 1: ACRONYM LIST

ARP	Autism Research Program
ASD	Autism Spectrum Disorders
CDA	Career Development Award
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	Food and Drug Administration
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code