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: W81XWH-21-ARP-CDA

Catalog of Federal Domestic Assistance Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), May 3, 2021
- **Invitation to Submit an Application:** June 2021
- **Application Submission Deadline:** 11:59 p.m. ET, August 5, 2021
- **End of Application Verification Period:** 5:00 p.m. ET, August 10, 2021
- **Peer Review:** September 2021
- **Programmatic Review:** November/December 2021

This program announcement must be read in conjunction with the General Application Instructions, version 603. 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

Applications to the Fiscal Year 2021 (FY21) Autism Research Program (ARP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP). The ARP was initiated in 2007 to provide support for research of exceptional scientific merit and innovation with high impact that focuses on autism spectrum disorder (ASD). Appropriations for the ARP from FY07 through FY21 totaled $104.4 million (M). The FY21 appropriation is $15M.

The ARP's vision is to improve the lives of individuals with ASD now, 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. Award History

The ARP Career Development Award mechanism is being offered for the first time in FY21.

II.B. Award Information

The FY21 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 FY21 ARP Career Development Award Areas of Interest.*** If the proposed study does not address an Area of Interest, an explanation of how the study addresses an important problem with respect to individuals with ASD must be provided.

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 FY21 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.

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 individuals with ASD 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 FY21 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 FY21 ARP seeks applications from investigators in the early stages of their ASD career. *The FY21 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.

FY21 ARP Career Development Award Areas of Interest: The FY21 ARP Career Development Award seeks applications from all areas of research. The ARP ***encourages*** applications that address critical needs of the ASD community in one or more of the FY21 ARP Career Development Award Areas of Interest:

  - Tests of implementation strategies to increase use of evidence-based practices
  - Assessment of novel therapeutics using valid preclinical models
  - Mechanisms of heterogeneous clinical expression of ASD
  - Environmental risk factors
  - Improve diagnosis across the life span
  - Factors promoting success in key transitions to independence for individuals living with ASD
  - Development of healthcare provider-focused training or tools to improve healthcare delivery for individuals with ASD across the life span and the continuum of care (i.e., primary care, urgent/emergent care, and disaster relief)
  - Cultural and socioeconomic factors in treatment efficacy, delivery, and access to services

- 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., sleep disturbances, gastrointestinal issues, inflammation, aggression, depression, anxiety, attention deficit, and seizures)
- Factors impacting quality of life during geographic relocation, such as military permanent change of station
- Long-term treatment outcomes from previous clinical trials for ASD core symptoms or to alleviate co-occurring conditions
- Create tools and strategies to increase the speed with which evidence-based practices are deployed in community-based settings
- Dissemination/implementation of clinically validated interventions
- Behavioral, cognitive, and other non-pharmacological therapies for ASD core symptoms or to alleviate co-occurring conditions
- Pharmacological, genetic, and other biological treatments for ASD core symptoms or to alleviate co-occurring conditions
- Improve diagnosis and access to services across the life span
- Interventions promoting success in key transitions to adulthood for individuals living with ASD
- Healthcare provider-focused training or tools to improve healthcare delivery for individuals with ASD across the life span and the continuum of care (i.e., primary care, urgent/emergent care, and disaster relief)
- Cultural, socioeconomic, and gender factors in diagnosis, treatment efficacy, delivery, and access to services
- Understanding heterogeneity in treatment response
- Pragmatic trials

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a "thing of value" to a "state, local government," or "other recipient" to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the Department of Defense (DOD) during project performance is the key factor in determining whether to award a

grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated direct costs budgeted for the entire period of performance for an FY21 ARP Career Development Award will not exceed **$500,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2022. For additional information refer to Section II.F.1, Federal Award Notices.

The CDMRP expects to allot approximately $1.6M to fund approximately two Career Development Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific 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 FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is ***not*** required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Early-phase, proof-of-principle clinical trials are allowed. ***A clinical trial is defined*** as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. 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).

Clinical research is defined as: (1) patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes research and health services research. ***Note:*** Studies that meet the requirements for IRB Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

Research Involving Animals: All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is ***not*** required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

Rigor of Experimental Design: All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in Landis, S.C., et al., A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards were written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derived from well-established best practices in research and should be applied consistently across basic and translational studies. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at http://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

Government Agencies Within the United States: Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this program announcement may be submitted by extramural and intramural organizations, these terms are defined below.

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

Intramural DOD Organization: A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission: Application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***

USAMRAA makes awards to eligible organizations, not to individuals.

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, 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.
- 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.
- 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.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at https://orcid.org/.

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 in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

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

II.D. Application and Submission Information

Submission of applications that are essentially identical or 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).

Extramural Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

Intramural DOD Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org.

Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.

II.D.1. Address to Request Application Package

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in Section II.G, Federal Awarding Agency Contacts.

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

Submission is a two-step process requiring both ***pre-application*** (eBRAP.org) and ***full application*** (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to Table 1, Full Application Guidelines).

The application title, eBRAP log number, 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 CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

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

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

No change in PI will be allowed after the pre-application deadline. If any other changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

PIs with an ORCID identifier should enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

  Submission of application information includes assignment of primary and secondary research classification codes, which may be found at https://ebrap.org/eBRAP/public/Program.htm. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

  Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

  Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on "Add Organizations to this Pre-application." The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

  It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

  Enter the name, organization, and role of all collaborators and key personnel associated with the application.

  FY21 ARP Programmatic Panel members should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

  Note: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

  - **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 to be reached. State the FY21 ARP Career Development Award Area(s) of Interest or another critical problem or question in ASD that will be addressed. 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. 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 of this study on the outcomes of individuals with ASD, 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.

- **Tab 6 – Submit Pre-Application**

  This tab must be completed for the pre-application to be accepted and processed.

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the 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:** How well the proposed project addresses the intent of the award mechanism and the vision of the ARP. Whether the proposed research addresses one or more of the FY21 ARP Career Development Award Areas of Interest or another central problem or issue in ASD. How well the rationale, study design, and specific aims support the project's objective. To what extent the research can be accomplished with the defined study population, if applicable.

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

- **Notification of Pre-Application Screening Results**

  Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated in Section I, Overview of the Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

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

Applications will not be accepted unless notification of invitation has been received.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (https://www.grants.gov/) for extramural organizations or through eBRAP (https://ebrap.org/) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be

completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the ***same version*** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the "Apply For Grants" page of Grants.gov (https://www.grants.gov/web/grants/applicants/apply-for-grants.html) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Do not password protect any files of the application package, including the Project Narrative.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for W81XWH-21-ARP-CDA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-21-ARP-CDA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end

Extramural Submissions	Intramural DOD Submissions
	date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. ***Note:*** If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to*** the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. ***Do not password protect any files of the application package, including the Project Narrative.***
Application Verification Period	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***. Your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.

Extramural Submissions	Intramural DOD Submissions
Further Information	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

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

- **Extramural Applications Only**

  SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

  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 4.

  For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full application package may not exceed 200 MB.

  - **Attachment 1: Project Narrative (page limit varies 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 that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

- **Page Limit:** Page limits vary:
  - **Projects without a clinical trial:** 8-page limit
  - **Projects with a clinical trial component:** 14-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 <u>without</u> 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 FY21 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 animals studies are proposed, describe how they will be conducted in accordance with the ARRIVE guidelines (https://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf). Additionally, describe how the proposed animal studies are designed to achieve reproducible and rigorous results, including the choice of model (including sex as a biological variable) and the endpoints/outcomes to be measured. 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. Detail how the proposed statistical analysis supports the relevance of any research outcomes to the FY21 ARP Career Development Award Area(s) of Interest or another critical problem or question in ASD identified. The inclusion of a biostatistician in the study team is encouraged.

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

- **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/or clinician 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 FY21 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 study 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 limitations 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.

  - Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-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. Detail how the proposed statistical analysis supports the relevance of any research outcomes to the FY21 ARP Career Development Award Area(s) of Interest or another critical problem or question in ASD identified. 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 career goals as an ASD researcher and/or clinician 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. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. 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 that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

  - **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 or not 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 or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- **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 suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- **Intellectual Property:** Information can be found in 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 how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- **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. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Programmatic reviewers typically do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

The technical abstract should address the following elements:

- **Research:**
  - Background: Present the ideas and reasoning behind the proposed project. Identify the FY21 ARP Career Development Award Area(s) of Interest or another critical problem or question in ASD to be addressed by the proposed research project.
  - Hypothesis(es) and/or Objective(s): State the objective(s) to be reached/hypothesis(es) to be tested. Provide evidence or rationale that supports the objective(s)/hypothesis(es).
  - Specific Aims: State the specific aims of this study.
  - Study Design: Briefly 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 individuals with ASD, 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. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information***. ***Do not duplicate the technical abstract.*** 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. Minimize the use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer community. Lay abstracts should be written using the outline below.

  - 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 FY21 ARP Career Development Award Area(s) of Interest or another critical problem or question in ASD the project addresses.
  - 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 individuals living with ASD 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 (three page limit): Upload as "SOW.pdf". The suggested Statement of Work (SOW) format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). Recommended strategies for assembling the SOW can be found at https://ebrap.org/eBRAP/public/Program.htm.

For the FY21 ARP Career Development Award, refer to either the "***Suggested SOW Strategy Clinical Research***" or "***Suggested SOW Strategy Generic Research***", whichever format is most appropriate for the proposed effort, and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attachment.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

– Include the name(s) of the key personnel and contact information for each study site/subaward site.

– Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

– For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug [IND] and Investigational Device Exemption [IDE] applications) by the FDA or other government agency.

- **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) (intellectual and/or tangible) and /or improved understanding of ASD that will be directly attributed to the results of the proposed research project (short-term impact). Compare the anticipated outcomes from the proposed project to ASD information/products currently available, if applicable. Describe the short-term and long-term impact of the expected outcomes of the research project on the ASD community, individuals with ASD and their quality of life, and the well-being of their families/caregivers.

  If a clinical trial component is proposed: Also explain how the aims of the project will have a significant clinical impact on individuals with ASD. 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 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).

  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, internal/external funding opportunities to be applied for).

- **Attachment 10: 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.

- Describe the overall regulatory strategy and product development plan that will support the planned product indication. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, and the types of FDA meetings that will be held/planned. Include considerations for compliance with current Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) guidelines.

- If an IND or IDE is required to initiate the proposed research project, it must be submitted to the FDA prior to the FY21 ARP Career Development Award application submission deadline. The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical trial. Provide the date of submission, application number, and sponsor for any existing FDA applications in place. If there are any existing cross-references in place, provide the application number and associated sponsor. Provide an explanation of the status of the application (e.g., past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold). Provide a summary of previous meetings with the FDA on development of this product, if appropriate. A copy of the Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application. The government reserves the right to withhold or withdraw funding if an IND or IDE 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 drug is to be used in the proposed clinical trial, describe the current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support phase 1 testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).

- 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 11: Representations, if applicable (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 5, Section B, Representations.

- **Attachment 12: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as "MFBudget.pdf".** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using "Suggested Collaborating DOD Military Facility Budget Format", available for download on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

  To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

  Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

  Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

  - PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

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

    – For extramural submissions, refer to the General Application Instructions, Section III.A.4 for detailed information.

    – For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

- 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".

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf". The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

- **Intramural DOD Collaborator(s):** Complete the "Suggested Collaborating DOD Military Facility Budget Format" and upload to Grants.gov attachment form as Attachment 12. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Verify the status of the applicant organization's Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that

determination as a basis for making a federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through April 2022, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity. Pre-application and application submissions are required. 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.

Applicant Verification of Full Application Submission in eBRAP

For Both Extramural and Intramural Applicants: eBRAP allows an organization's representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***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 application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Extramural Submission: The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.

Intramural DOD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business

Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

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

The anticipated direct costs budgeted for the entire period of performance will not exceed **$500,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **$500,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the total 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 multidisciplinary collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meeting(s) is to present project information or disseminate project results from the FY21 ARP Career Development Award.

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. ***For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.***

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, 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 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.
    - If applicable, to what extent the human subject population is appropriate for the study and whether there is clear access to the designated population.
    - 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.
    - How well the proposed statistical analysis supports the relevance of any research outcomes to the FY21 ARP Career Development Award Area(s) of Interest or another critical problem or question in ASD identified.
    - Whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed, if applicable.
- **Impact**

  Assuming the objectives/goals of the proposed research project are realized:
    - To what degree the proposed project is relevant to ASD.
    - How the anticipated outcomes from the proposed project compare to information/ products currently available, if applicable.

- To what extent the anticipated short-term outcome(s)/product(s) of the project may impact individuals with ASD, 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, individuals with ASD and the well-being of their families/caregivers.

- How well the proposed study addresses one or more of the FY21 ARP Career Development Award Areas of Interest or another critical problem or question in ASD.

- **Innovation**

  - To what extent the proposed research is innovative and, if successful, 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**

  - 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/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.
- **Clinical Strategy**
    - Whether the proposed clinical trial has sound rationale and methodology, and whether a description of the type of clinical trial to be performed (e.g., prospective, randomized, controlled) is provided.
    - To what extent the human subject population is described as being appropriate for the study and whether there is clear access to the designated population.
    - How well the recruitment plan and inclusion/exclusion criteria will support achieving the objective.
    - Whether the proposed intervention is feasible and endpoints are rational.
    - How well the applicant acknowledges potential problems and addresses alternative approaches.
    - Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
- **Clinical Impact**

  Assuming the objectives/goals of the proposed research project are realized:
    - Whether the aims of the project, if achieved, are likely to have a significant clinical impact on individuals with ASD.
    - How the potential outcomes of the proposed study will provide/improve short-term benefits for individuals with ASD.
    - 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 FY21 ARP Career Development Award Areas of Interest or another critical problem or question in ASD.

- **Innovation**
  - To what extent the proposed research, if successful, 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.
- **Statistical Plan**
  - To what degree the statistical plan and the rationale for the statistical methodology, including sample size projections, are adequate for the study proposed.
  - How well the proposed statistical analysis supports the relevance of any research outcomes to the FY21 ARP Career Development Award Area(s) of Interest or another critical problem or question in ASD identified.
  - Whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed, if applicable.
- **Regulatory Strategy**
  - Whether the application includes documentation that the study is exempt from FDA or other international agency regulation, or that the IND or IDE application (and/or international equivalent) has been submitted to the FDA and/or relevant international regulatory agency, as appropriate.
  - How well the documentation provided supports the feasibility of acquiring an active IND or IDE (and/or international equivalent) covering the proposed trial, if applicable.
  - For investigator-sponsored regulatory exemptions (e.g., IND, IDE, or other international equivalent), whether there is evidence of appropriate institutional support.
  - Whether plans to comply with GMP, GLP, and GCP guidelines are appropriate.
- **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**

  - 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/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 degree the study team's background, expertise and level of effort are appropriate to accomplish the proposed work.

In addition, the following **unscored** criteria will also contribute to the overall evaluation of the application:

- **Budget**

  - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.

  - Whether the budget is appropriate for the proposed research.

- **Environment**

  - To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).

  - Whether there is evidence for appropriate institutional commitment from each participating institution.

- If applicable, to what degree the intellectual and material property plan is appropriate.

- **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 mission of the DHP and FY21 ARP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio balance
  - Programmatic relevance to one or more of the FY21 ARP Career Development Award Areas of Interest or another critical problem or question in ASD
  - Relative impact and innovation

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, on behalf of the DHA and the OASD(HA). ***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.army.mil/about/2tierRevProcess. An information paper describing the funding recommendations and review process for the award mechanisms for the ARP will be provided to the PI and posted on the CDMRP website.

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 panel. Violations of confidentiality can result in the dissolving 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 another 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 200.88, 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 Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a federal awarding agency previously entered and is currently available in FAPIIS.

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.E.4. Anticipated Announcement and Federal Award Dates

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

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY21 funds are anticipated to be made no later than September 30, 2022. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

Pre-Award Costs: An institution of higher education, hospital, or other non-profit 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. Refer to the General Application Instructions, Section III.A.5.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds. 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.**

Federal Government Organizations: Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

II.F.1.a. 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. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Unless otherwise restricted, changes in PI or organization will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met.

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

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.2. 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 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the latest DoD R&D General Terms and Conditions; the USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions; and the USAMRAA General Research Terms and Conditions with For-Profit Organizations for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report will be required.

The Award Terms and Conditions will specify if more frequent reporting is required.

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

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

Awards resulting from this program announcement will incorporate 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 $10.0M are required to provide information to FAPIIS 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. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the "Synopsis" page for the program announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by 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 603a. The program announcement numeric version code will match the General Application Instructions version code 603.

II.H.2. Administrative Actions

After receipt of pre-applications or 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 exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- 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 Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- An FY21 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. ***A list of the FY21 ARP Programmatic Panel members can be found at https://cdmrp.army.mil/arp/panels/panels21***.
- 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.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- 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 may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The invited application proposes a different research project than that described in the pre-application.

- The PI does not meet the eligibility criteria.

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. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance **(extramural submissions only)**	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf".	
	Eligibility Statement: Upload as Attachment 8 with file name "Eligibility.pdf".	
	Research Outcomes Plan: Upload as Attachment 9 with file name "Outcomes.pdf"	
	Regulatory Strategy (if applicable): Upload as Attachment 10 with file name "Regulatory.pdf"	
	Representations (extramural submissions only): Upload as Attachment 11 with file name "RequiredReps.pdf" if applicable	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 12 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	

Application Components	Action	Completed
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget **(intramural submissions only)**	Suggested DOD Military Budget Format, including justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	

APPENDIX 1: ACRONYM LIST

ACURO	Animal Care and Use Review Office
ARP	Autism Research Program
ARRIVE	Animal Research: Reporting *In Vivo* Experiments
ASD	Autism Spectrum Disorder
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HRPO	Human Research Protection Office
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
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
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
VA	Department of Veterans Affairs