### I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

**Defense Health Program** 

**Congressionally Directed Medical Research Programs** 

# **Autism Research Program**

# **Idea Development Award**

**Announcement Type: Initial** 

Funding Opportunity Number: W81XWH-22-ARP-IDA

Assistance Listing 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 23, 2022

• Invitation to Submit an Application: June 27, 2022

• Application Submission Deadline: 11:59 p.m. ET, August 18, 2022

• End of Application Verification Period: 5:00 p.m. ET, August 23, 2022

• Peer Review: October 2022

• **Programmatic Review:** December 2022

This program announcement must be read in conjunction with the General Application Instructions, version 702. 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 2022 (FY22) Autism Research Program (ARP) are being solicited 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). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). 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 \$119.4 million (M). The FY22 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. FY22 ARP Idea Development Award Areas of Interest

The FY22 ARP Idea Development Award seeks applications from all areas of research. However, if the proposed research project does not address at least one of the FY22 ARP Idea Development Award Areas of Interest, justification should be provided that the proposed research addresses a critical problem, question, or need in ASD.

The ARP *encourages* applications that address the critical needs of the ASD community in one or more of the following areas:

- 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, socioeconomic, and gender factors in diagnosis, treatment efficacy, delivery, and access to services
- Mechanisms underlying sex differences in ASD (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

#### **II.A.2.** Award History

The ARP Idea Development Award mechanism was first offered in FY07. Since then, 597 Idea Development Award applications have been received, and 69 have been recommended for funding.

#### **II.B.** Award Information

The FY22 ARP Idea Development Award supports the development of innovative, high-risk/high-reward research that could lead to critical discoveries or major advancements that will accelerate progress in improving outcomes for individuals with ASD. *Applications are strongly encouraged to address one of the FY22 ARP Career Development Award Areas of Interest* or provide justification that the proposed research addresses a critical problem, question, or need in ASD. This award mechanism is designed to support innovative ideas with the potential to yield impactful data and new avenues of investigation.

#### Important aspects of the FY22 ARP Idea Development 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 articulated even if clinical impact is not an immediate outcome. A statistical plan is an important aspect of the FY22 ARP Idea Development Award to demonstrate the significance of any research outcomes or findings.
- **Innovation:** Research deemed innovative may represent a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other highly creative

qualities. Research may be innovative in study concept, research methods or technology, or adaptations of existing methods or technologies. Research that represents an incremental advance on previously published work is not considered innovative.

- **Personnel:** Personnel are considered a crucial element of the FY22 ARP Idea Development Award. The study team should have experience in ASD research. Inclusion of a biostatistician in the study team is encouraged.
- Research must be based on 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 Principal Investigators (PIs), 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.

Partnering PI Option: The FY22 ARP supports collaborative research to bring a new perspective to ASD research and/or facilitate progress in the field by combined efforts. Therefore, the ARP Idea Development Award mechanism includes a Partnering PI Option, which is structured so that **two investigators**, each of whom will be designated as a PI and receive a separate award, will work synergistically on a single project. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should collaborate to develop a synergistic project addressing one or more of the FY22 ARP Idea Development Award Areas of Interest or another critical problem, question, or need in ASD. Applications submitted by a mentor and trainee as Initiating PI and Partnering PI do not meet the intent of the Partnering PI Option. Multidisciplinary and multi-organizational projects are allowed.

Initiating and Partnering PIs each have different submission requirements, as described in <u>Section II.D.2</u>, <u>Content and Form of the Application Submission</u>; however, both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. It should be clear that both investigators have had an equal level of intellectual input and effort in developing the application. If recommended for funding, each PI will be named to an individual award within the recipient organization.

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 FY22 ARP Idea Development Award will not exceed \$550,000. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2023. For additional information refer to Section II.F.1, Federal Award Notices.

The CDMRP expects to allot approximately \$3.52M to fund approximately four Idea 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 FY22 funding opportunity will be funded with FY22 funds, which will expire for use on September 30, 2028.

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 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 up to 3 months to complete the HRPO regulatory review and approval process following submission of *all required and complete* documents to the HRPO. Refer to the General Application Instructions, Appendix 1, and the HRPO Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (<a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>) for additional information.

If the proposed research involves 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.

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. (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 deidentified specimens or data, if these sources are publicly available.

Clinical trials are not allowed under this award mechanism. 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.

PIs seeking funding for a clinical trial should utilize the FY22 ARP Clinical Trial Award (Funding Opportunity Number W81XWH-22-ARP-CTA).

**Research Involving Animals:** All research funded by the FY22 Idea Development Award mechanism 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 (<a href="www.nature.com/nature/journal/v490/n7419/full/nature11556.html">www.nature.com/nature/journal/v490/n7419/full/nature11556.html</a>). 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 2.0 (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE 2.0 guidelines can be found at <a href="https://arriveguidelines.org/arrive-guidelines.">https://arriveguidelines.org/arrive-guidelines.</a>

Investigators are encouraged to submit their data to the National Institute of Mental Health Data Archive (NDA), a secure bioinformatics platform for data sharing of ASD-related information, supported by the National Institute of Mental Health Data Archive. For more information, consult the NDA website at <a href="https://nda.nih.gov/">https://nda.nih.gov/</a>.

# **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 organizations 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: An 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.

The USAMRAA makes awards to eligible organizations, not to individuals.

#### II.C.1.b. Principal Investigator

Investigators at or above the level of Assistant Professor (or equivalent) may be named by the organization as the PI on the application.

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

The CDMRP strongly 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 <a href="https://orcid.org/">https://orcid.org/</a>.

#### **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 <u>Section II.H.2</u>, <u>Administrative Actions</u>, 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).

#### II.D.1. eBRAP and Grants.gov

**eBRAP** (<a href="https://ebrap.org">https://ebrap.org</a>) is a secure web-based system that allows PIs to submit their preapplications, view and verify extramural full applications submitted to Grants.gov (<a href="https://grants.gov">https://grants.gov</a>), receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

**Grants.gov** is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Contact information for the eBRAP Help Desk and the Grants.gov Contact Center can be found in <u>Section II.G</u>, <u>Federal Awarding Agency Contacts</u>.

#### 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.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 eBRAP Help Desk at <a href="help@eBRAP.org">help@eBRAP.org</a> or 301-682-5507 prior to the application submission deadline.

Partnering PI Option: The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI. The Partnering PI will then be notified of the pre-application submission separately by email. The Partnering PI must follow the link in the notification email in order to associate their full application package with that of the Initiating PI. After following the link, the Partnering PI must verify their contact information, organization, and designation as an extramural or intramural submission within eBRAP. If not previously registered, the Partnering PI must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI. Applicants are urged to complete these steps as soon as possible. If they are not completed, the Partnering PI will not be able to view and modify their application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Partnering PI's required full application package components to eBRAP.

#### 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 eBRAP 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 Initiating PI through eBRAP (<a href="https://eBRAP.org/">https://eBRAP.org/</a>). 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(s) 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 eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the eBRAP Help Desk at <a href="help@eBRAP.org">help@eBRAP.org</a> or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

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.

# When starting the pre-application, PIs should ensure that they have selected the appropriate application category in eBRAP:

- IDA Idea Development Award
- IDA-PO Idea Development Award Partnering Option

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 <a href="https://ebrap.org/eBRAP/public/">https://ebrap.org/eBRAP/public/</a>
<a href="Program.htm">Program.htm</a>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

# Tab 2 – Application Contacts

Enter contact information for the PIs. Enter the organization's Business Official(s) 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(s) 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.

<u>FY22 ARP Programmatic Panel members</u> should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to <u>Section II.H.2.c</u>, <u>Withdrawal</u>, or contact the eBRAP Help Desk at <u>help@eBRAP.org</u> or 301-682-5507.

The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section.

#### • 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:

- Research Idea: State the hypothesis to be tested or the objective to be reached. State the FY22 ARP Idea Development Award Area(s) of Interest that will be addressed. If the proposed project does not address one of the Idea Development Award Areas(s) of interest, provide justification that the proposed research addresses a critical problem, question, or need in ASD. Detail the ideas and rationale on which the proposed project is based. Concisely state the specific aims and provide a brief overview of the study design including a well-defined population, if applicable. This award cannot be used to conduct clinical trials or proof-of-concept intervention studies on human subjects.
- Impact: Describe the potential impact, both short and long term, of this study on the
  outcomes of individuals with ASD, their families/caregivers, and/or the
  understanding of ASD.
- **Innovation:** Describe how the proposed project is innovative and how the research represents more than an incremental advance on published data.
- **Personnel:** Clearly describe the ASD expertise of the proposed research team and how this will factor into the team's ability to successfully complete the project.

- 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 Defense Health Program (DHP) and the ARP, pre-applications will be screened based on the following criteria:

- Research Idea: Whether the proposed research addresses one or more of the FY22 ARP Idea Development Award Areas of Interest or, if not, whether justification was provided that the proposed research addresses a critical problem, question, or need in ASD. How well the rationale, study design, and specific aims support the project's objective. To what extent the research can be accomplished with the defined study population, if applicable.
- o **Impact:** What potential short- and long-term impact these studies will have on the outcomes of individuals with ASD, their families/caregivers, and/or the understanding of ASD.
- o **Innovation:** To what extent the research is innovative and represents more than an incremental advance on published data.
- **Personnel:** To what degree the PIs' and research team's backgrounds and ASD-related expertise are appropriate to successfully carry out the proposed research project.

#### • Notification of Pre-Application Screening Results

Following the pre-application screening, Initiating 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 <u>Section I, Overview of the Funding Opportunity</u>. 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 by the Initiating PI.

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 (<a href="https://grants.gov/">https://grants.gov/</a>) for extramural organizations or through eBRAP (<a href="https://ebrap.org/">https://ebrap.org/</a>) 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 (<a href="https://www.grants.gov/web/grants/applicants/apply-for-grants.html">https://www.grants.gov/web/grants/applicants/apply-for-grants.html</a>) 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** 

<b>Extramural Submissions</b>	Intramural DOD Submissions				
Application Package Location					
Download application package components for W81XWH-22-IDA-22 from Grants.gov (https://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-22-IDA-22 from eBRAP (https://ebrap.org).				
Full Application Pa	ackage 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 • Research & Related Subaward Budget Attachment(s) Form	<ul> <li>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:         <ul> <li>Attachments</li> <li>Key Personnel</li> <li>Budget</li> <li>Performance Sites</li> </ul> </li> <li>Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</li> </ul>				
Application Pac	kage 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	Submit package components to eBRAP ( <a href="https://ebrap.org">https://ebrap.org</a> ).  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.				

the "Forms" tab. Grants.gov recommends

submission of the application package at least

24-48 hours prior to the close date to allow time

eBRAP will notify your Resource Manager/

Comptroller/Task Area Manager or equivalent

Business Official by email. Do not password

# 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 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

#### **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.

Narrative.

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 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.

#### **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.

**Partnering PI Option:** The CDMRP requires separate full application package submissions for the Initiating PI and Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each full application package must be submitted using the unique eBRAP log number. *Note: All* 

associated applications (Initiating PIs and Partnering PIs) must be submitted by the full application submission deadline.

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 megabytes (MB), and the file size for the entire full application package may not exceed 200 MB.

- Attachment 1: Project Narrative (eight-page limit): Upload as "ProjectNarrative.pdf". The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.
  - Background: Present the ideas and reasoning behind the proposed research and include relevant literature citations. Describe and show the preliminary data to justify the rationale for the proposed project.
  - Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached. Describe how the project addresses one or more of the <u>FY22 ARP Idea</u>
     Development Award Areas of Interest or another critical problem or question in ASD.
  - Specific Aims: Concisely explain the project's specific aims to be supported by this application. If the proposed research is correlated with 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 problems and present alternative methods and approaches. *Partnering PI Option:* Describe how the research project is supported and strengthened by the proposed synergistic collaboration. If the project is multi-organizational, describe plans for communication between investigators at each organization.
- If animals studies are proposed, describe how they will be conducted in accordance with the ARRIVE 2.0 guidelines (<a href="https://arriveguidelines.org/arrive-guidelines">https://arriveguidelines.org/arrive-guidelines</a>). 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. Inclusion of a biostatistician on 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.
- Enrollment Table (if applicable): Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The Public Health Service (PHS) Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from eBRAP at <a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>
- 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 demonstrates 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.
- Intellectual Property: Information can be found in the Code of Federal Regulations,
   Title 2, Part 200.315 (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.
- 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.

Investigators are encouraged to submit their data to the National Institute of Mental Health Data Archive (NDA). For more information, consult the NDA website at <a href="https://nda.nih.gov/">https://nda.nih.gov/</a>

- 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.
  - Background: Present the ideas and reasoning behind the proposed research.
     Identify the FY22 ARP Idea Development Award Area(s) of Interest or provide justification that the proposed research addresses another critical problem, question, or need in ASD that will be addressed by the proposed research project.
  - **Hypothesis/Objective:** State the hypothesis to be tested or objective to be reached.
  - Specific Aims: State the specific aims of the 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.
  - Innovation: Briefly describe how the proposed project uses innovation to yield critical discoveries, new avenues of investigation, or major advancements to improve the understanding of ASD and ultimately to improve outcomes of individuals with ASD.
- 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.
  - Identify the <u>FY22 ARP Idea Development Award Area(s) of Interest</u> or another critical problem, question or need in ASD to be addressed by the proposed research project.
  - Describe the innovative aspects of the proposed research project.
  - Explain the impact that the proposed research project's results might have on the field of ASD research. Describe the impact, in the short and long term, on individuals with ASD, their families/caregivers, and/or the understanding of ASD.

• Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf". The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (<a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>). Recommended strategies for assembling the SOW can be found at <a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>.

For the Idea Development Award mechanism, refer to the "Suggested SOW Strategy Generic Research" document for guidance on preparing the SOW and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

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

- 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 currently available ASD information, products or treatments, if applicable. Describe the short-term and long-term impact of the expected outcomes of the research projects on the ASD community, individuals with ASD and their quality of life, and the well-being of their families/caregivers.
- 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: Accomplishments Statement (four-page limit): Upload as "Accomplishments.pdf". Provide ASD or other developmental disorder(s) research accomplishments of the Initiating PI and Partnering PI based on the outline below:
  - Past and current ASD or other developmental disorders research support from both federal and non-federal sources (as applicable) from the past 5 years.
  - Any honoraria, awards, or other distinctions received for work in ASD or other developmental disorders research from the past 5 years.
  - Any patents or other ASD or other developmental disorders research accomplishments from the past 5 years.
- 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: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.pdf". All extramural applicants must complete and submit the Required Representations template available on eBRAP (<a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- Attachment 11: 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 <a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>), 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.

- o 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 (<a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>) in eBRAP. The National Institutes of Health (NIH) 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".
  - 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.

**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.

Partnering PI Option: Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s) even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

**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.

o Intramural DOD Collaborator(s): Complete the "Suggested Collaborating DOD Military Facility Budget Format" and upload to Grants.gov attachment form as <a href="Attachment 11">Attachment 11</a>. (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.

Suggested DOD Military Budget Format: A military facility collaborating in the performance of the project (but not participating as a Partnering PI) should be treated as a subaward for budget purposes. *Note:* Applicants should complete a separate military 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]) (Attachment 11 to show all direct and indirect costs. 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.

# Application Components for Partnering PI if Applying Under the Partnering PI Option

The Partnering PI must follow the link in the email from eBRAP and, if not registered in eBRAP, complete the registration process prior to the application submission deadline in order to associate their full application package with that of the Initiating PI.

For the Partnering PI, the Initiating PI must identify if the Partnering PI will be named on an extramural or intramural application (in accordance with the guidelines in <u>Section II.C.1.a.</u>, <u>Organization</u>) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). The Partnering PI must verify their contact information and mode of submission within eBRAP to ensure proper submission of their application.

The application submission process for the Partnering PI uses an abbreviated full application package that includes:

#### • Extramural and Intramural Applications

#### **Attachments:**

- Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf". Refer to the General Application Instructions, Section III.A.2, for detailed information on completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.
- Attachment 10: Representations (extramural submissions only): Upload as "RequiredReps.pdf". All extramural applicants must complete and submit the Required Representations template available on eBRAP (<a href="https://ebrap.org/eBRAP/">https://ebrap.org/eBRAP/</a>

<u>public/Program.htm</u>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

 Attachment 11: Suggested Collaborating DOD Military Facility Budget Format: Upload as "MFBudget.pdf". Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

**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.

- o 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 (<a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.
- 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".
  - 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.

**Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section III.A.5, and for intramural submissions, refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf".

Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

**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 General Application Instructions, Section IV.A.5, for detailed information.

#### • Extramural Applications Only

#### Research & Related Subaward Budget Attachment(s) Form:

- 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.)
- o **Intramural DOD Collaborator(s):** Complete a separate DOD military 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]), and upload to Grants.gov attachment form as <a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>]), and upload to Grants.gov attachment form as <a href="https://ebrap.org/eBRAP/public/Program.htm">Attachment 11</a>. (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

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

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/SAM/) and receive confirmation of an "Active" status before submitting an application through Grants.gov. As published in the Federal Register, July 10, 2019, (https://www.federalregister.gov/documents/2019/07/10/2019-14665/unique-entity-id-standardfor-awards-management), the UEI for awards management generated through SAM will be used instead of the Data Universal Numbering System (DUNS) number as of April 2022. All federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI. USAMRDC will transition to use of the UEI beginning with FY22 announcements and utilize the latest SF424, which includes the UEI. The DUNS will no longer be accepted. Applicant organizations will not go to a third-party website to obtain an identifier. During the transition, your SAM registration will automatically be assigned a new UEI displayed in SAM. (For more information, visit the General Services Administration: https://www.gsa.gov/aboutus/organization/federal-acquisition-service/office-of-systems-management/integrated-awardenvironment-iae/iae-information-kit/unique-entity-identifier-update). Current SAM.gov registrants are assigned their UEI and can view it within SAM.gov. Authorized Organizational Representatives with existing eBRAP accounts should update their organizational profile to include the UEI prior to submission of the full application to Grant.gov (see Section II.D.4,

*Submission Dates and Times below).* Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

#### II.D.4. Submission Dates and Times

All submission dates and times are indicated in <u>Section I, Overview of the Funding Opportunity</u>. 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 PIs 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 \$550,000. 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 \$550,000 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.

Partnering PI: The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI's and the Partnering PI's applications will not exceed \$550,000. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the government will not exceed \$550,000 or use an indirect cost rate exceeding each organization's negotiated rate.

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

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 in addition to the required meeting described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY22 ARP Idea Development Award mechanism.

Must not be requested for:

Clinical trial costs

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

Note that high innovation and impact do not compensate for deficiencies in scientific merit.

#### 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.
- Partnering PI Option: How well the research project is supported by the nature of the synergistic collaboration. If the project is multi-organizational, how well the plans for communication between investigators is described.
- o If applicable, to what extent the human subject population is appropriate for the study and whether there is clear access to the designated population.
- If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research, if applicable.
- To what degree the statistical plan is appropriate for the experimental methodology being used.
- Whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed, if applicable.

• How well the applicant acknowledges potential problems and addresses alternative approaches.

#### Impact

- o To what degree the proposed project is relevant to ASD.
- How the anticipated outcomes from the proposed project compare to currently available ASD information, products, or treatments 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 <u>FY22 ARP Idea Development</u>
   <u>Award Areas of Interest</u> or justifies that the proposed research addresses a critical
   problem, question, or need in ASD.

#### Innovation

- To what extent the proposed research is innovative and will challenge existing paradigms or provide new paradigms, technologies, evidence-based diagnoses, and/or applications for ASD.
- o To what degree the proposed research represents more than a logical extension and/or incremental advance upon published data.

#### Personnel

- To what extent the PI's (if PPIO, both Initiating and Partnering PIs') expertise and skill in the research areas of ASD or other developmental disorders have been demonstrated as evidenced by funding, distinctions, awards, and/or patents.
- o To what extent the research team's background, expertise, and level of effort are appropriate to accomplish the proposed research.

#### • 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).

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

#### Environment

- Whether the scientific environment is appropriate for the proposed research.
- Whether the research requirements are supported by the availability of and accessibility to facilities and resources.
- To what extent the quality and level of institutional support are appropriate for the proposed research.

#### 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.

#### • 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 FY22 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 <u>FY22 ARP Idea Development Award</u> <u>Areas of Interest or another critical problem or question in ASD</u>
  - 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. *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 <u>Section II.E.1.b. Programmatic Review</u>. Additional information about the two-tier process used by the CDMRP can be found at <a href="https://cdmrp.army.mil/about/2tierRevProcess">https://cdmrp.army.mil/about/2tierRevProcess</a>. An information paper describing the funding recommendations and review process for the award mechanisms for the ARP will be provided to the PI(s) 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 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in the 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 <u>Section I, Overview of the Funding Opportunity</u>.

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 FY22 funds are anticipated to be made no later than September 30, 2023. 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 the 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 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

An organizational transfer of an award supporting the Initiating PI or Partnering PI is discouraged and will be evaluated on a case-by-case basis and only allowed 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.

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 <u>DoD R&D General Terms and Conditions</u>; the <u>USAMRAA</u> <u>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 <u>USAMRAA General Research Terms and Conditions with For-Profit Organizations</u>, for further information.</u>

*New Requirement:* Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI, Partnering PIs (if applicable), and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;
- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and
- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

#### 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 (<a href="https://ebrap.org/eBRAP/public/Program.htm">https://ebrap.org/eBRAP/public/Program.htm</a>) 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.

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

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

# **II.G. Federal Awarding Agency Contacts**

## II.G.1. eBRAP 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 eBRAP 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: <u>help@eBRAP.org</u>

#### **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 eBRAP 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 702a. The program announcement numeric version code will match the General Application Instructions version code 702.

#### **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 FY22 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 FY22 ARP Programmatic Panel members can be found at <a href="https://cdmrp.army.mil/arp/panels/panels22">https://cdmrp.army.mil/arp/panels/panels22</a>.
- 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 FY22, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<a href="https://cdmrp.army.mil/about/2tierRevProcess">https://cdmrp.army.mil/about/2tierRevProcess</a>). 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 preapplication.
- A clinical trial is proposed.
- Partnering PI Option: Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

#### 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	Initiating PI Completed	Partnering PI 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" Accomplishments Statement: Upload as Attachment 8 with file name "Accomplishments.pdf" Research Outcomes Plan: Upload as Attachment 9 with file name "Outcomes.pdf". Representations (extramural submissions only): Upload as Attachment 10 with file name "RequiredReps.pdf" Suggested Collaborating DOD Military Facility Budget Format: Upload as		
Research & Related Personal Data	Attachment 11 with file name "MFBudget.pdf" if applicable Complete form as instructed		

Application Components	Action	Initiating PI Completed	Partnering PI Completed
Research & Related	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the		
Senior/Key Person Profile (Expanded)	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	Complete as instructed. Attach Budget		
Budget (extramural submissions only)	Justification (BudgetJustification.pdf) to the appropriate field		
Budget (intramural submissions only)	Complete the Suggested DOD Military Budget Format, including justification		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form	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
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

FY Fiscal Year

HRPO Human Research Protection Office

IACUC Institutional Animal Care and Use Committee

IRB Institutional Review Board

M Million MB Megabytes

MIPR Military Interdepartmental Purchase Request
NDA National Institute of Mental Health Data Archive

NIH National Institutes of Health

ORCID Open Researcher and Contributor ID, Inc.

ORP Office of Research Protections
PDF Portable Document Format

PHS Public Health Service
PI Principal Investigator

SAM System for Award Management

SOW Statement of Work

STEM Science, Technology, Engineering, and/or Mathematics

URL Uniform Resource Locator
UEI Unique Entity Identifier

USAMRAA U.S. Army Medical Research Acquisition Activity

USAMRDC U.S. Army Medical Research and Development Command

USC United States Code