

# **Program Announcement**

for the

**Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

## **Autism Research Program**

### **Idea Development Award**

**Funding Opportunity Number: W81XWH-15-ARP-IDA**

**Catalog of Federal Domestic Assistance Number: 12.420**

#### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), June 10, 2015
- **Invitation to Submit an Application:** July 23, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, October 1, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, October 6, 2015
- **Peer Review:** December 2015
- **Programmatic Review** February 2016

*The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.*

***This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.***

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications to the Fiscal Year 2015 (FY15) Autism Research Program (ARP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The ARP was initiated in 2007 to provide support for innovative, high-impact research focused on autism spectrum disorder (ASD). Appropriations for the ARP from FY07 through FY14 totaled \$53.42 million (M). The FY15 appropriation is \$6M.

The ARP's vision is to improve the lives of individuals with ASD now by promoting innovative research that advances the understanding of ASD and leads to improved outcomes.

### B. FY15 ARP Areas of Interest

The FY15 ARP Idea Development Award seeks applications from all areas of basic and preclinical research, and *strongly encourages* applications that address the critical needs of the ASD community in the following areas:

- Assessment of novel therapeutics using valid preclinical models
- Environmental risk factors
- Mechanisms of heterogeneous clinical expression of ASD
- Mechanisms underlying conditions co-occurring with ASD (e.g., sleep disturbances, gastrointestinal issues, aggression, depression, anxiety)
- Factors promoting success in key transitions to independence for individuals living with ASD

### C. Award Information

The 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 autism. This award mechanism is designed to support innovative ideas with the potential to yield impactful data and new avenues of investigation. A statistical plan is an important aspect of the FY15 Idea Development Award to demonstrate the significance of any research outcomes or findings. *Past experimental research in the ASD research field or in other developmental disorders is crucial to the FY15 ARP Idea Development Award and will be evaluated in the selection process.*

**Important aspects of the FY15 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 lead ultimately to improved outcomes for individuals with ASD. The project's impact on both ASD research and patient care should be articulated, even if clinical impact is not an immediate outcome.
- **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 ARP Idea Development Award. The application should demonstrate the investigator's expertise in ASD or other developmental disorders through the Principal Investigator's (PI's) background, research team, or through collaboration. A biostatistician should be included in the study team. Collaborations should be demonstrated with written documentation.

***It is the responsibility of the PI to clearly and explicitly articulate the project's potential impact and innovation on outcomes in ASD.***

**Preliminary data relevant to the proposed research project are required.** Although the proposed research must have direct relevance to ASD, the required preliminary data, which may include unpublished results from the laboratory of the PI(s), research team, or collaborators named on this application, may be from outside the ASD research field. Applications should also be based on a sound scientific rationale that is established through logical reasoning and critical review and analysis of the literature.

**Multiple PI Option:** The FY15 ARP supports collaborative research to bring a new perspective to ASD research and/or facilitate progress in the field by combined efforts. Therefore, the FY15 ARP is offering a Multiple PI Option for this award mechanism. The Multiple PI Option 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 member of the team will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with the application. The other member will be referred to as the Partnering PI. ***Both investigators should collaborate to submit a single project addressing a central problem in ASD or one or more of the FY15 ARP Areas of Interest. Applications submitted by a mentor and trainee as Initiating PI and Partnering PI do not meet the intent of the Multiple PI Option.*** It should be clear that all investigators have an equal level of intellectual input and effort. Multidisciplinary and multi-organizational projects are allowed. ***A separate Grants.gov submission is required for each PI, even if the PIs are at the same organization.*** If the project is multi-organizational, PIs should include plans for communication between investigators at each organization. Additionally, participating organizations must be willing to resolve potential intellectual and material property issues and to remove any barriers that might interfere with achieving high levels of cooperation to ensure successful completion of this award.

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 5, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

***Clinical trials are not allowed under this award mechanism.*** A clinical trial is defined as a prospective accrual of patients where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. Refer to the General Application Instructions, Appendix 5, for additional information about studies involving human subjects, human subjects’ data, or human anatomical substances. Definitions of human subject use may be accessed at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/) and [https://cdmrp.org/files/forms/generic/Human\\_Subject\\_Research.pdf](https://cdmrp.org/files/forms/generic/Human_Subject_Research.pdf).

***PIs seeking funding for a clinical trial should utilize the FY15 ARP Clinical Trial Award (W81XWH-15-ARP-CTA).***

**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC 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. Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO must review and approve all animal use prior to the start of working with animals. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” ***Allow at least 3 to 4 months for regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 5, for additional information.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research. *Nature* 2012, 490: 187-191 ([www.nature.com/nature/journal/v490/n7419/full/nature11556.html](http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html)). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size

estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the ARRIVE (Animal Research: Reporting In Vivo Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at <http://www.nc3rs.org.uk/page.asp?id=1357>.

Investigators are encouraged to submit their data to the National Database for Autism Research (NDAR), a secure bioinformatics platform for data sharing of ASD-related information, supported by the National Institutes of Health. For more information, please consult the NDAR at <http://ndar.nih.gov>.

*The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 3, Section L.*

#### **D. Eligibility Information**

- Investigators at or above the level of Assistant Professor (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

#### **E. Funding**

Applications with a single PI or with the Multiple PI Option:

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$340,000**. Associated indirect costs can be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$340,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward (subgrant or subcontract) 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.
- **Multiple PI Option:** The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI and Partnering PI applications will not exceed **\$340,000**. The combined total direct costs of the Initiating PI and Partnering PI

awards will not exceed \$340,000 direct costs. If the Initiating PI's or Partnering PI's budgets contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget associated indirect rates in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the Government will not exceed **\$340,000** using an indirect rate exceeding each organization's negotiated rate. A separate award will be made to each PI's organization.

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

For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Clinical research costs
- Support for multidisciplinary collaborations and data sharing
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings

Must not be requested for:

- Clinical trial costs

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Section II.A. of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

***The CDMRP expects to allot approximately \$2.176M of the \$6M FY15 appropriation to fund approximately 4 Idea Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.***

## **II. 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.

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). Refer to the General Application Instructions, Section II.A. for registration and submission requirements for eBRAP and Grants.gov.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP. ***Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.***

**Multiple PI Option:** The FY15 ARP Idea Development Award mechanism is structured to accommodate up to two PIs. 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 the Partnering PI. Initiating and Partnering PIs each have different submission requirements; however, both PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required components. 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 this email and register with eBRAP in order to associate his/her Grants.gov application package with that of the Initiating PI.* Do not delay completing these steps. If this is not completed, the Partnering PI will not be able to view and modify his/her application submission in eBRAP.

#### **A. Where to Obtain the Grants.gov Application Package**

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-15-ARP-IDA in Grants.gov (<http://www.grants.gov/>).

#### **B. Pre-Application Submission Content**

All pre-application components must be submitted by the PI (for single PI applicants) or the Initiating PI (for applicants submitting under the Multiple PI Option) through eBRAP (<https://eBRAP.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations 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 PI must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

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):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
  - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF-424 form). The Business Official must either be selected from the eBRAP 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.

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

- Enter the name, organization, and role of all collaborators and key personnel associated with the application.
- FY15 ARP Integration Panel (IP) members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.
- **Multiple PI Option:** The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section.

- **Conflicts of Interest (COIs) – Tab 4**

- To avoid COIs during the screening and review process, list all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Pre-Application Files – Tab 5**

*Notes: Upload document(s) 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, etc.) 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 FY15 ARP Idea Development Award Area(s) of Interest (if applicable). Detail the ideas and reasoning on which the proposed project is based and how the research addresses a central problem in ASD. Concisely state the specific aims.
- **Impact:** Describe the potential impact of this study on the outcomes of individuals with ASD, their families, 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 research team and how this will factor into their ability to successfully complete the proposed research.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual documents* and are limited to:

- **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, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- **List of Abbreviations, Acronyms, and Symbols (no page limit):** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- **Key Personnel Biographical Sketches (five-page limit per individual):** Include biographical sketches for the PI and other key collaborators.

- **Submit Pre-Application – Tab 6**

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

### **Pre-Application Screening**

- **Pre-Application Screening Criteria**

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

- **Research Idea:** How well the proposed project addresses the intent of the award mechanism and the program. Whether the proposed research addresses one or more of the FY15 ARP Areas of Interest or a central problem or issue in ASD. How well the rationale and specific aims support the project's objective. To what extent the research can be accomplished with the defined study population, if applicable.
- **Impact:** What potential impact these studies will have on the outcomes of individuals with ASD, their families, and/or the understanding of ASD.
- **Innovation:** To what extent the research is creative and represents more than an incremental advance on published data.
- **Personnel:** To what degree the PI 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 on the [title page](#) of this Program Announcement/Funding Opportunity.

### **C. Full Application Submission Content**

*Applications will not be accepted unless the PI or Initiating PI has received notification of invitation.*

*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 Grants.gov application package provided in Grants.gov for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

**Note: *The Project Narrative and Budget Form cannot be changed after the application submission deadline.*** If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form 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.***

**Multiple PI Option:** The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and the Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned unique log numbers by eBRAP. Each Grants.gov application package must be submitted using the unique log number. **Note: *All associated applications (Initiating and Partnering PI) must be submitted by the Grants.gov deadline.***

#### **Application Components for Single PIs or the Initiating PI:**

**Grants.gov application package components:** For the Idea Development Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

- 1. SF-424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- 2. Attachments Form**

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov 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, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

The Project Narrative must include preliminary data originating from the PI(s) research team, or collaborator(s) that are relevant to the proposed project, but do not have to be from the ASD research field. The research strategy should be based on sound scientific rationale, outlined in detail, and fully supported by preliminary data and published reports.

Describe the proposed project in detail using the outline below.

- **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. How the project addresses one or more of the FY15 ARP Areas of Interest or a central issue 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 including appropriate controls, in sufficient detail for assessment. Address potential limitations and present alternative methods and approaches. **Multiple PI Option:** Describe how the research project is supported and strengthened by the proposed synergistic collaboration.
- **Data Analysis Plan:** Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis. Describe how the statistical plan is appropriate for the experimental methodology being used. Detail how the proposed statistical analysis supports the relevance of any research outcomes to the central problem or the FY15 ARP Area(s) of Interest identified. *If applicable*, describe how the human subject population is appropriate for the study and there is clear access to the designated population.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested 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 Patent Abstracts: Include a list of relevant publication URLs and/or patent abstracts. If publications 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/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual Property
  - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
  - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 3, Section L for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The technical abstract is used by all reviewers. Of particular importance, programmatic reviewers typically do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important. The technical abstract should be written using the outline below:

- Background: Present the ideas and reasoning behind the proposed research.
- Hypothesis/Objective: State the hypothesis/objective to be tested.
- 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 and/or an 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.”** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. Do not duplicate the technical abstract. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community. Include an overview of the proposed research project that can be readily understood by lay persons. Of particular importance, programmatic reviewers typically do not have access to the full application and therefore rely on the lay abstract for appropriate description of the project’s key aspects.

- Identify the FY15 ARP Area(s) of Interest addressed in the proposed research, if applicable, or the critical problem or question to be addressed by the proposed research project.
- Innovative aspect of the proposed research project.
- The impact that the proposed research project results might have on the field of ASD research. Describe the impact in the short or long term on individuals with ASD and how the research is relevant now.

- **Attachment 5: Statement of Work (SOW) (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 (<https://ebrap.org/eBRAP/public/Program.htm>). For the FY15 ARP IDA mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.

**Multiple PI Option:** *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and 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. Detail the anticipated outcome(s)/product(s) (intellectual and/or tangible) that will be directly attributed to the results of the proposed research project (short-term impact). Compare the anticipated outcomes from the proposed project to ASD information/products currently available, if applicable. Describe the short-term and long-term impact of the expected results of the study on the field and on the outcomes of individuals with ASD.

- **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 presents new paradigms in the field of ASD research. Investigating the next logical step or an incremental advancement on published data is not considered innovative.

- **Attachment 8: Performance History (four-page limit): Upload as “Performance.pdf.”**

Provide the performance history of the PI(s) based on the outline below:

- Current ASD or other developmental disorders support from both Federal and non-Federal sources from the past 5 years. Researchers new to the ASD field should describe related support from both Federal and non-Federal sources.
- Any honoraria, awards, or other distinctions received for work in ASD or other developmental disorders from the past 5 years.
- Any patents or ASD-related or other developmental disorders research accomplishments from the past 5 years.

- **Attachment 9: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (military health system facility, research laboratory, 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 the Collaborating DoD Military Facility Budget Form (available for download on the eBRAP “Funding Opportunities & Forms” web page), including a budget justification, for each Military Facility as

instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.

**3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. *Note: Some of the items in this attachment may be made available for programmatic review.*

- PI Biographical Sketch (five-page limit): Upload as “Biosketch\_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch\_LastName.pdf.”
  - **Multiple PI Option:** Include biographical sketches for the Initiating PI and the Partnering PI.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  - **Multiple PI Option:** Include previous/current/pending support for the Initiating PI and the Partnering PI.

**4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.5., 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.
- *The Initiating PI and the Partnering PI must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for the Partnering PI even if they are located within the same organization. The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI and the Partnering PI applications will not exceed \$340,000. The combined total direct costs of Initiating PI and Partnering PI awards will not exceed \$340,000 direct costs. 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 \$340,000 or using an indirect rate exceeding each organization’s negotiated rate.*

**5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.

- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

#### **Application Components for the Partnering PI Applying under the Multiple PI Option:**

*The Partnering PI MUST follow the link in the email from eBRAP and complete the registration process prior to the application submission deadline in order to associate his/her Grants.gov application package with that of the Initiating PI.*

The application submission process for the Partnering PI uses an abbreviated Grants.gov application package that includes:

- 1. SF-424 (R&R) Application for Federal Assistance Form**
- 2. Attachments Form**
  - Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.3., 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.*
- 3. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
  - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
  - The Initiating PI and Partnering PI must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages.* The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are at the same organization. The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI and Partnering PI applications will not exceed \$340,000. The combined total direct costs of Initiating PI and Partnering PI awards will not exceed \$340,000 direct costs. 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 \$340,000 or using an indirect rate exceeding each organization’s negotiated rate.
- 4. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.
- 5. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

#### **D. Applicant Verification of Grants.gov Submission in eBRAP**

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov.

Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation, 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.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

#### **E. Submission Dates and Times**

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in application rejection.

#### **F. Other Submission Requirements**

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

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

### **III. APPLICATION REVIEW INFORMATION**

#### **A. Application Review and Selection Process**

All applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP and ARP and to the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a nondisclosure statement 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 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 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 Title 18 United States Code 1905.

## **B. Application Review Process**

- 1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, of which Scientific Merit is more significant than the remaining criteria, which are of equal importance:

*Note that innovation and impact do not compensate for deficiencies in scientific merit. A statistician will be included on all scientific review panels.*

- **Scientific Merit**

- To what extent a clear hypothesis is stated and supported through scientific rationale, preliminary data, and referenced literature.
- How well the hypothesis or objectives, specific aims, and experimental design are developed.
- If the application includes a Partnering PI, how well the research project is supported by the nature of the collaboration.
- If applicable, to what extent the human subject population is described as being appropriate for the study and there is clear access to the designated population.
- To what degree the statistical plan is appropriate for the experimental methodology being used.
- How well the proposed statistical analysis supports the relevance of any research outcomes to the central problem or FY15 ARP Area(s) of Interest identified.
- Whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed.
- How well the applicant acknowledges potential problems and addresses alternative approaches.
- Whether the applicant demonstrates the availability of tissue, data, or human subjects, if applicable.

- **Impact**

- To what degree the proposed project is relevant to ASD.
- How the anticipated outcomes from the proposed project compare to information/products currently available, if applicable.

- To what extent the anticipated short-term outcome(s)/product(s) may impact the ASD community.
- To what degree the anticipated long-term gains from this research course may impact the ASD community.
- To what extent the proposed project, if successful, will ultimately improve the outcomes of individuals with ASD and well-being of their families/caregivers.
- **Innovation**
  - To what extent the proposed research, if successful, will challenge existing paradigms, or provide new paradigms, technologies, evidence-based diagnoses, molecules, and/or applications for ASD.
  - To what degree the proposed research represents more than a logical extension and/or incremental advance upon published data.
- **Personnel**
  - To what extent the research team's background and expertise are appropriate to accomplish the proposed research.
  - To what extent the biostatistician is included in the study team to improve the overall analysis and course of the proposed research.
  - To what extent the levels of effort by the initiating and partnering PI (if applicable) and other key personnel are appropriate for successful conduct of the proposed research.
  - To what extent the initiating PI and partnering PI (if applicable) has demonstrated expertise and skill in the research areas of ASD or developmental disorders as evidenced by funding, distinctions, awards, and/or patents.

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.
  - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**

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

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

**a. Ratings and evaluations of the peer reviewers**

**b. Relevance to the mission of the DHP and FY15 ARP, as evidenced by the following:**

- Adherence to the intent of the award mechanism
- Program portfolio balance
- Programmatic relevance to the FY15 ARP Areas of Interest or a crucial issue in ASD
- Relative impact and innovation

**C. Recipient Qualification**

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

**D. Application Review Dates**

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

**E. Notification of Application Review Results**

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.

**IV. ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

**A. Rejection**

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

- Preproposal Narrative is missing.
- Preproposal Narrative is over the page limit.

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.
- **Multiple PI Option:** Both Initiating and Partnering PI applications are not submitted by the deadline.

## **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.

## **C. Withdrawal**

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

- A FY15 ARP IP 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 FY15 ARP IP members can be found at <http://cdmrp.army.mil/arp/panels/panels15.shtml>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- 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).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- If a clinical trial is proposed, the application will be withdrawn.
- The PI does not meet the eligibility criteria.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

## **D. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution 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.

## **V. AWARD ADMINISTRATION INFORMATION**

### **A. Award Notice**

Awards will be made no later than September 30, 2016. Refer to the General Application Instructions, Appendix 3, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

### **B. Administrative Requirements**

Refer to the General Application Instructions, Appendix 3 for general information regarding administrative requirements.

### **C. National Policy Requirements**

Refer to the General Application Instructions, Appendix 4 for general information regarding national policy requirements.

### **D. Reporting**

Refer to the General Application Instructions, Appendix 3, Section I, for general information on reporting requirements.

### **E. Award Transfers**

Refer to the General Application Instructions, Appendix 3, Section M, for general information on organization or PI changes.

## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

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

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

### **B. Grants.gov Contact Center**

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

Phone: 800-518-4726

Email: [support@grants.gov](mailto: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/Funding Opportunity 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.***

## VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Initiating PI Completed	Partnering PI Completed
SF-424 (R&R) Application for Federal Assistance		Complete form as instructed.		
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."		
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."		
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."		
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."		
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."		
	6	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."		
	7	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf."		
	8	Performance History: Upload as Attachment 8 with file name "Performance.pdf."		
	9	Collaborating DoD Military Facility Budget Form(s): Upload Attachment 9 with file name "MFBudget.pdf," if applicable.		
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.		
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.		
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.		
Research & Related Budget		Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Project/Performance Site Location(s) Form		Complete form as instructed.		
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.		