

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Congressionally Directed Medical Research Programs

Parkinson's Research Program

Early Investigator Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-17-PRP-EIRA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), August 17, 2017
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, September 5, 2017
- **Application Submission Deadline:** 11:59 p.m. ET, August 31, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, September 5, 2017
- **Peer Review:** October 2017
- **Programmatic Review:** December 2017

This Program Announcement must be read in conjunction with the General Application Instructions, version 20170516. The General Applications 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 2017 (FY17) Parkinson's Research Program (PRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA). The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). The PRP (formerly the Neurotoxin Exposure Treatment Parkinson's Research Program) was initiated in FY97 to provide support for research of exceptional scientific merit leading to an understanding of the cause, prevention, and treatment of the loss of dopaminergic neurons in the substantia nigra that results in Parkinson's disease. Appropriations for the PRP from FY97 through FY16 totaled \$404.75 million (M). The FY17 appropriation is \$16M.

The PRP challenges the scientific community to develop impactful research that will advance the understanding of, and ultimately end, Parkinson's disease.

The vision of the PRP is to stop Parkinson's disease by funding research through a partnership of scientists and consumers.

II.A.1. FY17 PRP Focus Areas

Consistent with the mission of the FY17 PRP to support research to understand, prevent, diagnose, and treat Parkinson's disease in patients, including Service members and Veterans, investigators **are required** to address at least one of the following FY17 PRP Focus Areas:

- Mechanisms of neuroplasticity in the Parkinson's disease brain
- Studies to identify gene-environment interactions in Parkinson's disease cohorts (applications addressing this focus area have an additional submission requirement; see [Attachment 9](#))
- Pathophysiological implications of tau protein in Parkinson's disease

II.B. Award Information

The PRP Early Investigator Research Award (EIRA) mechanism is being offered for the first time in FY17.

The PRP Early Investigator Research Award supports Parkinson's disease-focused research opportunities for individuals in the early stages of their careers, under the guidance of a designated Mentor. The Early Investigator is considered the Principal Investigator (PI) of the application and must exhibit strong potential for, and commitment to, pursuing a career as an investigator at the forefront of Parkinson's disease research; however, the PI is not required to have previous Parkinson's disease research experience. Clinical fellows applying to the PRP

EIRA mechanism should be specializing in movement disorders. Applications must include at least one Mentor, appropriate to the proposed research project, who has experience in Parkinson's disease research and mentoring as demonstrated by a record of active funding, recent publications, and successful mentorship. The selected Mentor(s) should also demonstrate a clear commitment to the development of the PI toward independence as a Parkinson's disease researcher.

The following are important aspects of the EIRA:

- *All applications for the Early Investigator Research Award are to be written by the PI, with appropriate direction from the Mentor(s).*
- **Principal Investigator:** The EIRA supports early-career investigators exploring innovative, high-impact ideas or new technologies applicable to Parkinson's disease research and/or patient care. The PRP seeks applications from investigators from a broad spectrum of disciplines including, but not limited to, basic science, engineering, bioinformatics, population science, translational research, and clinical research. The application should demonstrate the PI's potential for, and commitment to, pursuing a career in Parkinson's disease research under the guidance of a designated Mentor(s).
- **Development Plan:** The PI must outline an individualized, Parkinson's disease-focused researcher development plan. The researcher development plan should include a clearly articulated strategy for acquiring the necessary skills, competence, and expertise that will enable the PI to successfully complete the proposed research project and foster the PI's development as an independent Parkinson's disease researcher. An environment appropriate to the proposed mentoring and research at the PI's institution must be clearly described. Additional necessary resources and/or mentorship may be provided through collaboration(s) with other institutions. If the PI will be utilizing resources at another institution to successfully complete the proposed project, then the PI is strongly encouraged to designate a co-Mentor at the collaborating institution.
- **Focus Area:** The proposed research **must** address at least one of the FY17 PRP Focus Areas.
- **Research Approach:** Experimental strategies may be novel or may be based on strong rationale derived from previously published data, presented preliminary data, or literature review. The feasibility of the research design and methods should be well defined, and a clear plan should be articulated as to how the proposed goals of the project can be achieved.

Preliminary data are not required. Any unpublished, preliminary data provided should originate from the PI, Mentor(s), or member(s) of the collaborating team. The preliminary data must support the feasibility of the study.

The anticipated total costs budgeted for the entire period of performance for an FY17 PRP EIRA will not exceed **\$321,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this Program Announcement/Funding Opportunity. A clinical trial is defined as a prospective accrual of patients (human subjects) in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. For more information on clinical trials and clinical research overall, a Human Subject Resource Document is provided on the CDMRP electronic Biomedical Research Application Portal (eBRAP) system at (<https://ebrap.org/eBRAP/public/Program.htm>).

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) 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. 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/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. Refer to the General Application Instructions, Appendix 1, 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.

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

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, including amendments to ongoing projects. 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 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

Use of Military and VA Populations or Resources: If applicable, access to target military or Department of Veterans Affairs (VA) patient population(s) or resources should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included in Attachment 2 for studies involving active duty military, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement 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 2, Section K.

Awards will be made no later than September 30, 2018. For additional information refer to [Section II.F.1, Federal Award Notices](#).

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including 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 academia, biotechnology companies, foundations, Government, and research institutes. *Extramural Submission: Application submitted by a non-DoD organization to Grants.gov.*

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

civilian employee working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.

Note: Applications from an intramural organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

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

II.C.1.b. Principal Investigator:

The investigator must be a postdoctoral or clinical fellow within three years of advanced degree or residency training (or equivalent) as of the application deadline. Clinical fellows must be specializing in movement disorders.

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

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Extramural 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.

Each investigator may submit only one PRP Early Investigator Research Award application as a PI.

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

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

II.D. Application and Submission Information

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

Extramural Submission is defined as an application submitted by a non-DoD organization to Grants.gov.

Intramural Submission is defined as an application submission by a DoD organization for an intramural investigator, who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.

II.D.1. Address to Request Application Package

Submitting Extramural and Intramural Organizations: Pre-application content and forms can be accessed at eBRAP (<https://eBRAP.org>).

Submitting Extramural Organizations: Full application packages can be accessed at Grants.gov.

Submitting Intramural DoD Organizations: Full application packages can be accessed at eBRAP.org.

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

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

Submission is a two-step process requiring both ***pre-application*** and ***full application*** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (<https://eBRAP.org/>).

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.

Full Application Submission: Full applications must be submitted through the online portals as described below.

Submitting Extramural Organizations: Full applications from extramural organizations must be submitted through Grants.gov. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in [Section II.C.1, Eligible Applicants](#).

eBRAP allows intramural organizations to submit full applications following pre-application submission.

For both Extramural and Intramural applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. 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. 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.

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 application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

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

During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed 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 may result in delays in processing.**

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

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

PIs, Mentors, 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 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):

- **Tab 1 – Application Information**

- **Tab 2 – Application Contacts**

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

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) 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 including mentor(s) associated with the application.

FY17 PRP Programmatic Panel members should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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 pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Pre-applications or applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

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

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). Refer to the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the Focus Area(s) under which the application will be submitted and the name(s) of the Mentor and, if applicable, co-Mentor(s). LOIs are used for

program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

- **List of Individuals Providing Confidential Letters of Recommendation:** Enter contact information for the individuals, who will provide letters of recommendation. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload his/her letter. The letters of recommendation must include one from the Mentor and at least one from the co-Mentor (if applicable) or other independent researcher who has had scientific knowledge of and interaction with the PI. *The total number of letters must not exceed three.*

- **Tab 6 – Submit Pre-Application**

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

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

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. Refer to the General Application Instructions, Section III, for details on compatible Adobe software.

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 (<http://www.grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines. For the Early Investigator Research Award, additional application components are also required and should be submitted as directed in the [Additional Application Components](#) section.

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

Extramural organizations, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

| Extramural Submissions | Intramural DoD Submissions |
|--|---|
| Application Package Location | |
| Download application package components for W81XWH-17-PRP-EIRA from Grants.gov (http://www.grants.gov). | Download application package components for W81XWH-17-PRP-EIRA from eBRAP (https://ebrap.org). |
| Full Application Package Components | |
| <p>SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.</p> | <p>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.</p> |
| <p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • R&R Subaward Budget Attachment(s) Form (if applicable) • Additional Application Component(s) | <p>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:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites • Other <p>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.</p> |
| Application Package Submission | |
| <p>Submit package components to Grants.gov (http://www.grants.gov).</p> <p>If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget need 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.</p> | <p>Submit package components to eBRAP (https://ebrap.org).</p> <p>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 “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the application submission deadline.</p> |

| Extramural Submissions | Intramural DoD Submissions |
|--|--|
| <u>Application Verification Period</u> | |
| 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, <i>with the exception of the Project Narrative and Budget Form</i> , may be modified. | After eBRAP has processed the full application, the organizational Resource Manager/ Comptroller or equivalent Business Official and PI will receive an 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, <i>with the exception of the Project Narrative and Budget Form</i> , may be modified. |
| Further Information | |
| Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements. | Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements. |

The organization’s Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.

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 (R&R) 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 incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (seven-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 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.

Describe the proposed project in detail using the outline below. *The Project Narrative must be written by the PI while also showing evidence of appropriate direction from the Mentor(s).*

- **Principal Investigator:** The PI should describe his/her career goals and how the proposed research project and mentoring experience will promote his/her development toward becoming an independent Parkinson’s disease researcher. The PI should discuss his/her research plans and career plans after the completion of this award.
- **Mentor(s):** For each Mentor or co-Mentor, describe his/her background and experience in Parkinson’s disease research. Explain how he/she will assist the PI throughout the period of performance in developing toward independence in Parkinson’s disease research. Describe the track record of each Mentor for mentoring young investigators in Parkinson’s disease research.
- **Research Strategy:**
 - Describe the proposed research project, including the background, hypothesis/purpose and rationale, broad objectives and specific aims, and methods (including appropriate controls).
 - Explain how this research strategy will meet the research goals and milestones. Address potential pitfalls and problem areas and present alternative methods and approaches.

- If the methodology is new or unusual, provide sufficient details for evaluation.
 - Describe the statistical plan including power analysis that reflects sample size projections that will address the hypothesis and/or the objectives of the project. If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE guidelines (http://www.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf).
 - Describe the availability of the necessary resources, including human subjects or human anatomical samples; include a detailed plan for the recruitment of subjects or the acquisition of samples, if applicable. Address any potential ethical concerns. Outline how approvals from local IRBs will be obtained and how the informed consent process will be initiated, as applicable.
 - Describe how cell line authentication and/or statistical rigor of preclinical experiments have been incorporated into the study design, if applicable.
- **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. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

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 Patents: 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, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.
- Intellectual Property: Information can be found in 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.
 - 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.
- Transcripts: Include a copy of the PI’s transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The Government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts. If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), complete and include the Academic Statement (available for download on the Full Announcement page in Grants.gov) in place of the transcript.
- **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.

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. Describe the proposed research project including the following elements:

– **Research Plan:**

- Background: Present the ideas and reasoning behind the proposed project.
- Objective/Hypothesis: State the hypothesis (or hypotheses) to be tested or the objective to be reached.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design to include methodology, statistical analysis, and appropriate controls.
- Focus Area: State which of the FY17 PRP Focus Area(s) will be addressed.

– **Personnel:**

- The PI should describe his/her career goals and potential for a career at the forefront of Parkinson's disease research.
- The PI should describe how the proposed research project will prepare him/her to make valuable contributions to the understanding and management of Parkinson's disease.

– **Impact:** Summarize the impact of the proposed research, if successful, on the understanding, prevention, diagnosis, and/or treatment of Parkinson's disease.

- **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.*** 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 community.

- Clearly describe, in a manner readily understood by readers without a background in science or medicine, the rationale, objective, and aims of the project.
- Describe the relationship of the proposed work to the specific Focus Area(s) of this Program Announcement/Funding Opportunity.

- Describe the ultimate applicability of the research.
 - What types of patients will it help and how will it help them?
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected time it may take to achieve a patient-related outcome?
 - What is the likely impact of this study on the understanding, prevention, diagnosis, and/or treatment of Parkinson’s disease?
- Describe the PI’s career goals in Parkinson’s disease research.
 - How does the research plan support the PI in achieving these goals?
 - How does the mentorship and researcher development plan support the PI in achieving these goals?
- **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 Early Investigator Research Award mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching.

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

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

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

Briefly state the methods to be used.

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

Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.

If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the U.S. Food and Drug Administration or other Government agency.

- **Attachment 6: Researcher Development Plan (two-page limit):** Upload as “ResearchDev.pdf.”
 - Clearly articulate a strategy for acquiring the necessary skills, competence, and expertise to successfully complete the proposed research project.
 - Indicate how the individualized researcher development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in the field of Parkinson’s disease, and effectively prepare him/her for a career as an independent Parkinson’s disease researcher.
 - Describe how the researcher development plan is supported by the environment and mentorship, including a description of ongoing Parkinson’s disease research at the institution. Include a description of the environment of any collaborating institutions that will augment the lack of specific resources at the PI’s primary institution (if applicable). Include information on collaborations with other investigators, seminars, workshops, and other opportunities to interact with leaders in the Parkinson’s disease field. Do not reference or include members of the [FY17 PRP Programmatic Panel](#).
- **Attachment 7: Impact Statement (one-page limit):** Upload as “Impact.pdf.” Articulate the pathway to making a clinical impact for individuals with, or at risk for, Parkinson’s disease. Describe the near-term impact as well as the long-term impact. The near-term impact will be anticipated outcome(s)/product(s) from the proposed research. The long-term impact may be beyond the scope of the proposed research. Describe how the proposed research addresses at least one of the FY17 PRP Focus Areas.
- **Attachment 8: Eligibility Statement (one-page limit):** Upload as “Eligibility.pdf.” Use the Eligibility Statement template (available for download on the Full Announcement page under this Funding Opportunity on Grants.gov) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met by the time of application submission.
- **Attachment 9: Data and Research Resources Sharing Plan:** Upload as “ResourceSharing.pdf.” (*Attachment 9 is only required for applications proposing studies to identify gene-environment interactions in Parkinson’s disease cohorts but encouraged for all applications.*) Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Attachment 10: DoD Military 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 DoD Military Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural and Intramural Applications –**

Research & Related Senior/Key Person Profile (Expanded): 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.

- PI Biographical Sketch (five-page limit): Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (PDF) that is not editable.

- 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.”

Include the Mentor’s (and co-Mentor’s, if applicable) biographical sketch.

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

Include the Mentor’s (and co-Mentor’s, if applicable) previous/current/pending support.

Research & Related Budget: 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.

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

Project/Performance Site Location(s) Form): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

R&R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.6, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)

Intramural DoD Collaborator(s): Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 10. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

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|--|
| Additional Application Components |
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In addition to the complete Grants.gov application package, Early Investigator Research Award applications also require the following components:

- **Confidential Letters of Recommendations**

The letters of recommendation should be provided on letterhead, signed, and uploaded as PDF files to eBRAP by 5:00 p.m. ET on the [last day of the verification period](#). The PI should monitor whether the letters have been received in eBRAP by viewing the status in the “Pre-Application Files” tab of the pre-application; however, the PI will not be able to view these letters.

The confidential letters should include the following (2 pages per letter recommended):

- ***A confidential letter of recommendation from the Mentor (and another from the co-Mentor, if applicable)***, describing his/her commitment to the PI’s career development and mentorship in Parkinson’s disease research. Mentor letters should address the following:
 - The PI’s potential to become a successful and independent Parkinson’s disease researcher;
 - The proposed interactions of the Mentor with the PI during the PI’s research project;
 - The mentoring environment, including ongoing Parkinson’s disease research in the Mentor’s laboratory and in the organization as a whole, resources available, and how this environment will promote the development of the PI as a Parkinson’s disease researcher;
 - The degree to which the PI participated in the project development and application preparation, and the degree to which the PI will participate in the execution of the application if funded.

- ***Additional confidential letters of recommendation (one is required; maximum of two).*** Additional letters should describe the PI's unique qualifications and accomplishments that highlight his/her potential for success in pursuing a career in Parkinson's disease research. Specifically, each letter should offer the writer's perspective on:
 - The PI's qualifications, characteristics, and achievements;
 - The PI's potential for productivity and desire for establishing a successful and independent career in Parkinson's disease research;
 - The relevance of the proposed research project to developing the PI's career in Parkinson's disease research; and
 - The suitability of the Mentor(s) and the research environment for providing the PI with a solid foundation to support an independent career in Parkinson's disease research.

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

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. Verify the status of the applicant's organization's Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a submitted application. 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 retrieved files against the specific Program Announcement 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. *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 Budget Form cannot be changed after the application submission deadline.

II.D.5. Funding Restrictions

The maximum period of performance is **2** years.

The anticipated total (direct plus indirect) costs budgeted for the entire period of performance will not exceed **\$321,000**. 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 **\$321,000** total 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 **2** years.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- PI salary or stipend
- Research supplies
- Workshop costs
- Publication costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for one investigator to travel to one scientific/technical meeting per year

Must not be requested for:

- Mentor or other salary
- Clinical trial costs
- Equipment

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). 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 fund transfer. Intragovernmental only funding to intramural DoD and other Federal agencies will be managed through a direct fund 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.4, 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.4.*

The CDMRP expects to allot approximately \$1.6M of the \$16M FY17 PRP appropriation to fund approximately five Early Investigator Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.

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 listed in decreasing order of importance:

- **Research Team**
 - **Principal Investigator**
 - How the PI's achievements (as reflected by academic performance, awards, honors, and/or previous publications and funding) indicate the potential for a successful career as a Parkinson's disease researcher.
 - To what extent the PI's stated career goals demonstrate a strong personal commitment to pursuing an independent career as a leader in Parkinson's disease research.
 - To what extent the letters of recommendation from the Mentor(s) and others support the PI's potential for a highly productive career as a Parkinson's disease researcher.
 - Whether the PI's proposed level of effort, if not 100%, is appropriate for successful completion of the proposed work.

- **Mentor(s)**
 - Whether there is at least one Mentor who is an established Parkinson’s disease researcher, as evidenced by a demonstrated record of active funding and recent publications in Parkinson’s disease research.
 - How the Mentor’s (and co-Mentor’s, if applicable) own experience indicates the potential of the Mentor(s) to supervise the PI’s research project.
 - To what extent the Mentor’s track record for training young investigators indicates the potential for successful mentoring of the PI in Parkinson’s disease research.
 - Whether the Mentor letter(s) indicate a high level of commitment to the PI’s development as a Parkinson’s disease researcher.
 - Whether the quality of the application suggests that the Mentor(s) provided appropriate guidance in its preparation.
- **Researcher Development Plan**
 - How well the PI has outlined an individualized plan that will enable him/her to acquire the necessary skills, competence, and expertise to successfully complete the proposed research project.
 - How well the individualized researcher development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in Parkinson’s disease research, and effectively prepare him/her for a career as an independent Parkinson’s disease researcher.
 - To what extent the scientific environment at the primary institution and collaborating institution(s) is appropriate for the proposed research and career development activities, including professional interaction with established Parkinson’s disease researchers.
 - To what degree the proposed research project and mentoring experience will bring the PI to the forefront of Parkinson’s disease research.
- **Research Strategy and Feasibility**
 - How well the scientific rationale supports the proposed research and its feasibility, as demonstrated by a critical review and analysis of the literature, Parkinson’s disease-relevant preliminary data (if included), and/or logical reasoning.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
 - How well the study is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, power analysis, and data handling.

- How well any animal studies proposed are designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.
- For studies to identify gene-environment interactions in Parkinson's disease cohorts, how well the plans to share data and resources are described.
- To what extent the proposed research project is feasible as described.
- How well the application identifies potential problems and addresses alternative approaches.
- Whether the application has provided sufficient evidence to support availability of and access to the populations/samples required for the study, and whether the plan for acquiring the necessary research resources is sufficient for the proposed research project (if applicable).
- Whether experiments to address the clinical relevance of the anticipated findings have been incorporated into the study design (if applicable).
- **Impact**
 - To what degree the proposed research, whether in the near term or long term, would make a major impact in the understanding, prevention, diagnosis, and/or treatment of Parkinson's disease.
 - How well the proposed research addresses one or more of the FY17 PRP Focus Areas.

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

- **Environment**
 - To what extent the research requirements are adequately supported by the availability and accessibility of facilities and resources (including collaborative arrangements and/or intellectual property plans as applicable).
 - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Budget**
 - Whether the total maximum costs are equal to or less than the allowable total maximum 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 Congressional intent and the vision of the PRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio balance
 - Programmatic relevance to the FY17 PRP Focus Areas
 - Relative impact

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 of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the PRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a 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 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 (currently \$150,000) 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 (FAPIS).

An applicant, at its option, may review FAPIS, accessible through SAM, and submit comments to FAPIS on any information about itself that a Federal awarding agency previously entered and is currently available in FAPIS.

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 (DoDGAR), Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

Extramural Organizations: An assistance agreement (grant or cooperative 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. 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). Substantial involvement may include 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.

After email notification of application review results through the 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.

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 documents.

Intramural Organizations: Awards 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 managers (RM).

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

II.F.1.a. Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

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 DoDGAR found in 32 CFR, Chapter 1, 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 [USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations](#) and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements.

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

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose semiannually information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations are available in OAR Article I, Section B, in the [July 2016 R&D General Terms and Conditions](#). The applicable Terms and Conditions for for-profit organizations are available in Section 34 of the [February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations](#).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

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

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

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov

application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

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

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20170516b. The Program Announcement numeric version code will match the General Applications Instructions version code 20170516.

II.H.2. Administrative Actions

After receipt of applications, the following administrative actions may occur:

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the application:

- An FY17 PRP 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 FY17 PRP Programmatic Panel members can be found at <http://cdmrp.army.mil/prp/panels/panels17>.***
- The application fails to conform to this Program Announcement 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).
- 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 FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, 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.
- 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.
- If the same PI submits multiple applications to the FY17 PRP EIRA mechanism, all applications except for the first one received will be withdrawn.
- An application that does not address an FY17 PRP Focus Area will be withdrawn.
- An application for which the PI does not meet the eligibility criteria will be withdrawn.

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

| Application Components | Action | Completed |
|---|---|-----------|
| SF424 (R&R) Application for Federal Assistance (Extramural submissions only) | Complete form as instructed. | |
| Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only) | Complete these 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." | |
| | Researcher Development Plan: Upload as Attachment 6 with file name "ResearchDev.pdf." | |
| | Impact Statement: Upload as Attachment 7 with file name "Impact.pdf." | |
| | Eligibility Statement: Upload as Attachment 8 with file name "Eligibility.pdf." | |
| | Data and Research Resources Sharing Plan (<i>required for studies to identify gene-environment interactions</i>): Upload as Attachment 9 with file name "ResourceSharing.pdf," if applicable. | |
| | DoD Military Budget Form(s): Upload as Attachment 10 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 (Extramural submissions only) | Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field. | |
| Budget (Intramural submissions only) | Complete the DoD Military Budget Form and justification. | |
| Project/Performance Site Location(s) Form | Complete form as instructed. | |
| R&R Subaward Budget Attachment(s) Form, if applicable | Complete form as instructed. | |
| Additional Application Components | Action | Completed |
| Confidential Letters of Recommendation | Confirm upload to eBRAP. | |

APPENDIX 1: ACRONYM LIST

| | |
|----------|---|
| ACURO | Animal Care and Use Review Office |
| CDMRP | Congressionally Directed Medical Research Programs |
| CFR | Code of Federal Regulations |
| DHA | Defense Health Agency |
| DHP | Defense Health Program |
| DoD | Department of Defense |
| DoDGAR | Department of Defense Grant and Agreement Regulations |
| DUNS | Data Universal Numbering System |
| eBRAP | Electronic Biomedical Research Application Portal |
| EC | Ethics Committee |
| EIRA | Early Investigator Research Award |
| 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 |
| LOI | Letter of Intent |
| M | Million |
| MIPR | Military Interdepartmental Purchase Request |
| OASD(HA) | Office of the Assistant Secretary of Defense for Health Affairs |
| OMB | Office of Management and Budget |
| ORP | Office of Research Protections |
| PI | Principal Investigator |
| PRP | Parkinson's Research Program |
| RDT&E | Research, Development, Test, and Evaluation |
| RM | Resource Manager |
| SAM | System for Award Management |
| SOW | Statement of Work |
| USAMRAA | U.S. Army Medical Research Acquisition Activity |
| USAMRMC | U.S. Army Medical Research and Materiel Command |
| USC | United States Code |
| VA | Department of Veterans Affairs |