

Program Announcement

for the

Department of Defense

Congressionally Directed Medical Research Programs

Neurotoxin Exposure Treatment Parkinson's Research Program

Depression Research Award

Funding Opportunity Number: W81XWH-15-NETPR-DRA

Catalog of Federal Domestic Assistance Number: 12.420

Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), December 2, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, December 16, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, December 21, 2015
- **Peer Review:** March 2016
- **Programmatic Review:** May 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) Neurotoxin Exposure Treatment Parkinson's Research (NETPR) program are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA). The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP).

The NETPR 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 result in Parkinson's disease (PD).

Appropriations for the NETPR from FY97 through FY14 totaled \$372.5 million (M). The FY15 appropriation is \$16M.

PD is considered to be the result of both inherent genetic heritage and environmental impacts impinging on heritable expression. Heterogeneity of the affected population results in distinctive vulnerability subsets in the population, all of whom are diagnosed by late-stage expression of the motor dysfunction, noted clinically by tremor (usually a resting tremor, although more than 25 percent of patients with PD have an associated action tremor), rigidity (stiffness of the limbs and trunk), bradykinesia (slowness of movement), and postural instability (impaired balance and coordination, which results in difficulty with walking and gait) and response to treatment with L-DOPA.

Peer-reviewed studies indicate a number of military risk factors for the development of PD. Among the most significant risk factors are: Exposure to agricultural-type chemicals (including pesticides, insecticides, and solvents); traumatic injury to the head; prolonged physiologic or mental stress; repeated or prolonged disruption of sleep architecture; and repeated or prolonged disruption of autonomic nervous function. These may immediately impact both physical and cognitive performance as well as predisposing susceptible Warfighters to development of neurodegenerative conditions.

The mission of the NETPR Program is to:

- Identify surrogate markers of PD,
- Correlate distinctive clinical features with specific clusters of these markers, and
- Develop interventions in bio-molecular pathways that link markers and expressed clinical features in order to prevent or halt progression of the disease or improve the quality of life for PD patients.

B. Areas of Emphasis

Depression is both an epidemiological identified risk factor for development of PD and a comorbid condition that affects an increasing proportion of individuals as PD progresses.

This funding opportunity is specifically focused on the following Areas of Emphasis on depression as a risk factor and/or co-morbidity in PD:

- Delineation of metabolic pathways that may lead to identification of molecular markers and/or therapeutic targets associated with modulation or control of serotonergic or non-serotonergic activity.
- Characterization of underlying genetic mechanisms associated with development of depression, or characterization of intersects between genetic mechanisms associated with depression and other known risk factors (as identified in published literature) for development of PD.
- Identification of surrogate markers in the blood for identification, diagnosis, susceptibility, maintenance, or progression of depression associated with neurodegeneration.

Innovative applications not focused on the Areas of Emphasis noted above are acceptable, provided the application:

- Is specifically related to development or progression of depression as a non-motor manifestation of PD and/or is clearly linked to depression as a risk factor for initiation or progression of PD; and
- Provides a strong rationale for relevance to the mission of the NETPR Program.

C. Award Information

The Depression Research Award mechanism is being offered for the first time in FY15.

The intent of the NETPR Depression Research Award is to support research efforts that will make significant advancements in the understanding of serotonergic and non-serotonergic molecular pathways identified with depression and associated biologic phenomena that link the pathways to other risk factors (e.g., disruption of sleep architecture, exposure to long-term psychological and physiological stress, dysautonomia, and traumatic brain injury) for development and progression of PD. It is expected that research supported by this award will lead to the development of new treatments or the improvement of current treatments for depression, specifically in individuals with, or at risk for, PD. It is anticipated that projects will emphasize preclinical research in human populations, animal studies, or *in silico* retrospective studies. Preliminary data are required.

Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity. 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.

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.

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). 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.

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

- Independent investigators at or above the level of Associate Professor (or equivalent) are eligible to submit an application.
- 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

- The maximum period of performance is 3 years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$1.5M**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$1.5M** 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.

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (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.

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 supplies
- Clinical research costs
- Travel costs to attend scientific/technical meetings
- Travel between collaborating organizations
- Data sharing costs associated with the execution of a data sharing plan.
- Publication costs for peer-reviewed articles.
- Equipment costs of not more than ten percent (10%) of the total direct costs.
- Support for multidisciplinary collaborations

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 SAM registration and a 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 \$2.5 M of the \$16M FY15 appropriation to fund approximately one (1) Depression Research Award application, 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 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.

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-NETPR-DRA in Grants.gov (<http://www.grants.gov/>).

B. Pre-Application Submission Content

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

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 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 NETPR 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 or 301-682-5507.
- **Conflicts of Interest (COIs) – Tab 4**
 - 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**
 - **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. LOIs are used for program planning purposes (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.
- **Submit Pre-Application – Tab 6**
 - This tab must be completed for the pre-application to be accepted and processed.

C. Full Application Submission Content

Applications will not be accepted unless the PI has submitted an LOI prior to or at the deadline for submission of the LOI.

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.*

Grants.gov application package components: For the Depression Research 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 (12-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.

Describe the proposed project in detail using the outline below.

- **Background:** Briefly describe the ideas and reasoning on which the proposed work is based. Provide a sound scientific rationale for the proposed project as established through a critical review and analysis of published literature. Provide sufficient preliminary data to support the feasibility and rationale of the proposed work.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims to be funded by this award.
- **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Explain how this research strategy will meet the research goals and milestones. Describe the statistical plan including power analysis, as appropriate, for the research proposed. Address potential pitfalls and problem areas and present alternative methods and approaches. 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). If human subjects or human biological samples will be used, describe the study population and include a detailed plan for the recruitment of human subjects or the acquisition of samples. *Clinical trials are not allowed under this funding opportunity.*

- **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: 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.

- 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.

Describe the proposed research project including the following elements:

- **Background:** Present the ideas and reasoning behind the proposed project.
- **Hypothesis (or Objective):** State the hypothesis (or hypotheses) to be tested or the objective to be reached.
- **Specific Aims:** State the specific aims of the study.
- **Research Strategy:** Briefly describe the research strategy to include methodology, statistical analysis, and appropriate controls.
- **Outcomes:** Concisely describe the expected research outcomes of the work and their relationship to the Area/s of Emphasis addressed.

- **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.

The lay 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 lay abstract for appropriate description of the project’s key aspects.

- Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers who do not have a background in science or medicine.
- Describe the relationship of the proposed work to the specific Area of Emphasis of this funding opportunity.
- Describe the expected impact that the proposed work will have in the area of depression as a co-morbidity or as a risk factor for PD.
- Describe how the research outcomes will be shared with other researchers and with the PD community.

- **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 Depression 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. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.

The SOW should indicate a feasible plan and timeline to conduct the research and should provide clearly defined milestones.

- **Attachment 6: Area/s of Emphasis Statement (one-page limit): Upload as “Emphasis.pdf”:** Describe how the proposed work will directly address one of the Areas of Emphasis. If the proposed work does not address one of the Areas of Emphasis, describe how it is specifically related to development or progression of depression as a co-morbidity of PD and/or is clearly linked to depression as a risk factor for PD. Explain how the proposed work is relevant to the mission of the NETPR Program.
 - **Attachment 7: Impact Statement (one-page limit): Upload as “Impact.pdf”:**
 - Describe the short- and long-term impact of this study on PD research and PD patient treatment and/or quality of life. Specifically explain how the proposed work will make significant advancements in the understanding and/or treatment of depression as a co-morbidity or risk factor of PD.
 - Describe the expected benefit or impact of the proposed work for the civilian, military, and Veteran communities.
 - **Attachment 8: Outcomes Statement (one-page limit): Upload as “Outcomes.pdf”:** Clearly state how outcomes from the research relate to specific non-motor features of PD. Describe what research resources and tools will be developed with potential benefit in the treatment or improvement of quality of life for the PD population. State how information and research resources generated under the funded work will be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.
 - **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 (5-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 (5-page limit each): Upload as “Biosketch_LastName.pdf.”
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

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.

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.

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 applications are evaluated by a panel of 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 Commanding General of the United States Army Medical Research and Materiel Command, based on (a) technical merit and (b) the relevance to the mission of the USAMRAA, CDMRP, NETPR, 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>.

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 criteria, which are of equal importance:

- **Relevance:**
 - How well the proposed work adheres to the definition of PD as the condition resulting from the loss of dopaminergic neurons in the Substantia nigra.
 - How well the proposed research adheres to one or more of the Program Announcement’s stated Areas of Emphasis.

- If the application does not address a stated Area of Emphasis, how well the application:
 - Is specifically related to development or progression of depression as a co-morbidity of PD and/or is clearly linked to depression as a risk factor for initiation or progression of PD.
 - Provides a strong rationale for relevance to the mission of the NETPR Program.
- **Research Strategy and Feasibility:**
 - How well the scientific rationale supports the project and its feasibility, as demonstrated by preliminary data and a critical review and analysis of the literature.
 - How well the hypotheses or objectives, aims, experimental design, methods, statistical plan, and analyses are developed.
 - How well the design of the study (or studies) supports reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - How well the SOW indicates a feasible plan and timeline to conduct the research.
- **Impact:**
 - To what degree the proposed work will have a short- and long-term impact on PD research and PD patient treatment and/or quality of life.
 - To what degree the proposed work will make significant advancements in the understanding and/or treatment of depression as a co-morbidity or risk factor of PD.
 - Whether the proposed research has the potential to benefit the civilian, military, and Veteran communities.
- **Outcomes:**
 - Whether there is a clear statement of what research resources and tools will be developed with potential benefit in the treatment or improvement of quality of life for the PD population.
 - To what degree the information and research resources generated under the funded work will be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.
- **Personnel:**
 - How appropriate are the research team's background and expertise to accomplish the proposed work.

- To what extent the levels of effort by the key personnel are appropriate to ensure the success of this project.

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

- **Budget:**
 - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Environment:**
 - To what degree the scientific environment is appropriate for the proposed research.
 - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
 - To what degree the quality and extent of organizational support are appropriate.
 - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.

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 Congressional intent and the NETPR Program, as evidenced by the following:**
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Relative impact on depression as a co-morbidity or risk factor of PD

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 applications from Grants.gov, the following administrative actions may occur:

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.

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 application:

- An FY15 NETPR Program Integration Panel (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 NETPR IP members can be found at <http://cdmrp.army.mil/netpr/panels/panels15>.**
- 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.
- An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.
- If a clinical trial is proposed, the application will be withdrawn.

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.

In addition to written progress reports, in-person presentations by the PI or a designate may be requested.

Copies of all scientific publications and presentations as a result of this funding are required to be attached as appendices to submitted reports.

E. Award Transfers

Changes in PI are only allowed under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

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

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

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	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	Area/s of Emphasis Statement: Upload as Attachment 6 with file name "Emphasis.pdf."	
	7	Impact Statement: Upload as Attachment 7 with file name "Impact.pdf."	
	8	Outcomes Statement: Upload as Attachment 8 with file name "Outcomes.pdf."	
	9	Collaborating DoD Military Facility Budget Form(s): Upload as 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 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.	