I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Parkinson's Research Program

Investigator-Initiated Research Award

Announcement Type: Initial

Funding Opportunity Number: HT942524PRPIIRA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), July 17, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, August 6, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, August 12, 2024
- **Peer Review:** October 2024
- **Programmatic Review:** January 2025

This program announcement must be read in conjunction with the General Application Instructions, version 901. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Parkinson's Research Program (PRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. In FY22, Congress transitioned the Neurotoxin Exposure Treatment Parkinson's program to PRP and broadened the research from neurotoxin exposure treatment Parkinson's disease (PD) research to all types of PD research. Appropriations for the PRP from FY22 through FY23 totaled $32 million (M). The FY24 appropriation is $16M.

The vision of the PRP is to improve the health and lives of people with Parkinson's disease through innovative, clinically meaningful treatments.

The mission of the PRP is to support high impact Parkinson's research that alters disease progression, improves disease symptoms, and develops treatments that benefit Service members and their families, Veterans, and the general public.

II.A.1. FY24 PRP Focus Areas

To meet the intent of the funding opportunity, all applications **MUST** address at least one of the following **FY24 PRP Focus Areas:**

- Biological mechanisms or biomarkers (e.g., fluid, imaging, tissue, devices) of unmet medical needs that could lead to the development of treatments for PD. Applications focused on laboratory models through to human participants would be considered. Examples of unmet medical needs of interest include, but are not limited to:
    - Non-motor symptoms:
        - Cognitive
        - Psychiatric
        - Sleep and circadian rhythms disruptions
        - Autonomic
    - Motor symptoms:
        - Tremor
        - Gait and balance

  - Dystonia
  - Dyskinesia

- Interventions that address unmet medical needs of PD that include both clinical and preclinical models. Examples of interventions of interest include, but are not limited to:
  - Non-pharmacological
  - Surgical
  - Non-surgical devices
  - Non-invasive central nervous system stimulation
  - Biologicals
  - Pharmacological

II.A.2. Award History

The PRP Investigator-Initiated Research Award (IIRA) mechanism was first offered in FY22. Since then, 111 PRP IIRA applications have been received, and eight have been recommended for funding.

II.B. Award Information

The PRP IIRA supports highly rigorous, multidisciplinary, high-impact research projects that have the potential to make an important contribution to Parkinson's research. This award mechanism supports the full spectrum of research from basic science through clinical research.

The following are important aspects of the IIRA:

- **Research Strategy and Feasibility:** The scientific rationale and experimental methodology should demonstrate critical understanding and in-depth analysis of the neurodegenerative effects of PD. 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 to support feasibility are required. Any unpublished, preliminary data provided should originate from the laboratory of the Principal Investigator (PI) or member(s) of the research team. The preliminary data must support the feasibility of the study. ***Clinical trials may be supported by this award mechanism and require the submission of Attachment 8, Clinical Strategy Statement.***

- **Impact:** The proposed research should impact an area of paramount importance in PD.

- The application must clearly and explicitly describe the potential short-term and long-term impact of the proposed study and convey its level of significance.

- The research should benefit individuals with PD.

- **Focus Area:** The proposed research ***must*** address at least one of the FY24 PRP Focus Areas.

- **Principal Investigator and Research Team:** The PRP seeks applications from investigators working in 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 that the research team's background is appropriate to successfully achieving the proposed research and contributing to the field of PD research.

- ***New for FY24:*** The PRP IIRA includes an option for more than one PI. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as Partnering PI(s), with a maximum of two Partnering PIs. All PIs should contribute significantly to the development and execution of the proposed research project. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PI(s), refer to Section II.D.2, Content and Form of the Application Submission.

- **The PRP IIRA requires that the Initiating PI dedicate at least 15% of their full-time professional effort to this award during the award period.**

- ***Clinical trials are allowed.***

Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of active-duty Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

The CDMRP also encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

Applications from investigators within the military Services and applications involving multidisciplinary collaborations among academia, industry, the military Services, the U.S. Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique resources or databases, the application must

describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.

(2) Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

The anticipated total costs budgeted for the entire period of performance for an FY24 PRP IIRA Award should not exceed **$2.0M**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately $12.0M to fund approximately six PRP IIRA applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is

anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

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

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

II.C.1.b. Principal Investigator

Independent investigators at or above the level of Assistant Professor (or equivalent) are eligible to be named by the applicant organization as the PI or as the Initiating or Partnering PI for applications submitted to the Partnering Option.

Each investigator may be named to no more than two PRP IIRA applications as either the Initiating PI or a Partnering PI.

The PRP IIRA requires that the Initiating PI dedicate at least 15% of their full-time professional effort to each IIRA during the award period.

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

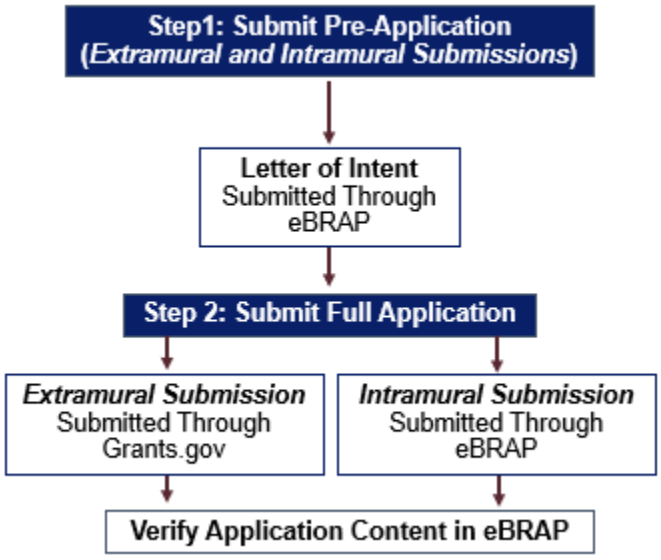
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural versus intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Application Submission Workflow



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For

example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524PRPIIRA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524PRPIIRA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

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

Submitting applications that 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).

Unnecessary duplication of funding, or accepting funding from more than one source for the same research, is prohibited. See the CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 PRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

All pre-application components must be submitted by the PI or Initiating PI through eBRAP (https://eBRAP.org/), including the submission of contact information for each Partnering PI if exercising the Partnering PI Option.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for each PI, the Business Official(s), performing

organization(s), and contracting organization(s) must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

Partnering PI Option: After the Initiating PI confirms submission of the pre-application, the Partnering PI(s) will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI(s) must follow the link in the notification email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PI(s) must register in eBRAP.

After associating the pre-application with their eBRAP account, the Partnering PI(s) should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated with their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).

Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI. Partnering PIs are urged to complete these steps as soon as possible. If they are not completed:

- The Partnering PI(s) will not be able to view and modify their full application during the verification period in eBRAP.
- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.

When starting the pre-application, applicants will be asked to select a "Mechanism Option." Please be sure to select the correct option appropriate to your pre-application:

Application Includes:	Select Option:
Single PI and No Clinical Trial	No Option
Single PI and Clinical Trial	Clinical Trial
Initiating PI and Partnering PI with No Clinical Trial	Partnering PI Option
Initiating PI and Partnering PI With Clinical Trial	Clinical Trial – Partnering PI Option

II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for detailed instructions regarding pre-application submission):

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the FY24 PRP Focus Area(s) under which the application will be submitted.

  LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. ***An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.***

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

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations ***must*** be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

II.D.2.b.ii. Full Application Submission Components for the PI or Initiating PI

Partnering PI Option: The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Each full application package must be submitted using the unique eBRAP log number received by the Initiating and Partnering PIs during pre-application submission. ***All associated applications (the Initiating PI's and each Partnering PI's) must be submitted by the full application submission deadline.***

Each application submission must include the completed full application package for this program announcement. See Section II.H.3 of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B, for detailed information.

(b) 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 2.

- **Attachment 1: Project Narrative (twelve-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands 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.

  - **Rationale:** Clearly articulate the scientific rationale for the proposed research project. Cite relevant literature. ***The presentation of preliminary and/or published data to support the proposed research project is required.***

  - **Hypothesis:** State concisely the new concept, theory, paradigm, and/or method that addresses an important problem in PD research and/or patient care.

  - **Specific Aims:** Concisely explain the proposed research project's specific aims to be funded by this application. If the proposed research project is part of a larger study, present only tasks that this award would fund.

  - **Research Strategy:**

    - Describe how each study is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, power analysis, and data handling.

    - Describe how any animal studies proposed are designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.

    - Clearly articulate why the proposed research project is feasible as described.

    - Identify potential problems and address alternative approaches.

    - Describe the statistical plan for the research proposed, as appropriate.

    - Describe how the study design addresses the clinical relevance of the anticipated findings (if applicable).

    - For applications proposing non-exempt clinical research, describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in

terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects.

- **Project Coordination and Communication:** Describe plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all PIs and organizations participating in the project. For multi-institutional studies, provide an organizational chart that identifies key members of the study team and provides an outline of the governing structure.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

  There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

  References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.

  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 government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

  Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

  Letters of Organizational Support: Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

  Letters of Collaboration *(if applicable)*: Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural

DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

Inclusion Enrollment Plan *(only required if clinical research is proposed; for applications proposing clinical trials, this plan should be included in Attachment 8, Clinical Strategy Statement)*: Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

Intellectual Property: Information can be found in 2 CFR 200.315, "Intangible Property."

- **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Commercialization Strategy *(if applicable)*:** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

Data and Research Resources Sharing Plan: Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users; and including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to the CDMRP Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about the CDMRP's expectations for making data and research resources publicly available.

Use of DOD Resources *(if applicable)*: Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

Use of VA Resources *(if applicable)*: Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

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

  Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

  Background: Present the ideas and rationale supporting the proposed research project.

  Research Questions and/or Concepts: State the research question/concept to be tested. Provide evidence or rationale that supports the research question/concept.

  Specific Aims: State the specific aims of the study.

  Study Design: Briefly describe the study design to include methodology, statistical analysis, and appropriate controls.

  Impact: Briefly describe how the proposed research project will have short-term and/or long-term impact on PD research and/or patient care.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

  Lay abstracts should address the points outlined below ***in a manner that will be readily understood by readers without a background in science or medicine***. Avoid overuse use of scientific jargon, acronyms, and abbreviations.

  Clearly describe the rationale and objective for the proposed research project.

Do not duplicate the technical abstract.

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 are the likely contributions of the proposed research project to advancing the field of PD research and/or patient care?

- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

  For the IIRA, refer to either the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" or "Example: Assembling a Generic Statement of Work," whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit the SOW as a PDF file.

  Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and [each or the] Partnering PI should be clearly noted for each task.

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** Articulate the pathway to making a clinical impact for individuals with, or at risk for, PD.

  Clearly and explicitly describe how the proposed research will contribute to making an impact for individuals with or at risk for PD.

  Describe both the short-term and long-term impacts toward the PRP's mission of supporting Parkinson's research.

  - The short-term impact will be the 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 FY24 PRP Focus Areas.

- **Attachment 7: Research Team Statement (one-page limit): Upload as "Team.pdf".** Discuss the qualifications of the research team and each individual's specific

contributions to the project, including how the appropriate expertise is incorporated to address the research question and enable the success of the proposed project.

Discuss how the PI's and other key personnel's experience, expertise, and record of accomplishment demonstrate their ability to successfully complete the proposed research project.

Explain how the levels of effort by the PI and other key personnel are appropriate to ensuring success of the proposed research project. Clearly state if the PI or other key personnel are not receiving salary from the award but providing the required effort.

Address the requirement for at least 15% dedication of full-time professional effort of the PI to this award.

Partnering PI Option:

- Describe how the partners bring different strengths to the application.
- Explain how their combined expertise will better address the research question.
- **If applicable,** describe the composition of the clinical trial team. Provide details on how the team (including investigators, study coordinator, biostatistician) possesses the appropriate expertise in PD and in conducting clinical trials.

- **Attachment 8: Clinical Strategy Statement*, if applicable* (no page limit): Upload as "Clinical.pdf". If funds for a clinical trial are requested, this attachment is required.**

  – Describe the rationale for the proposed clinical trial. Provide a description of the intervention and the endpoints to be measured. Describe any biomarkers specific to the intervention and demonstrate their potential to improve patient selection, efficiency, and interpretation as well as de-risk and improve design of anticipated larger scale trials. Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.

  – If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically, identify the portions of the study that would be supported with funds from this award.

  – Provide detailed plans for initiating the clinical study within the first year, including U.S. Food and Drug Administration (FDA) Investigational New Drug/Investigational Device Exemption (IND/IDE) application submission plans within 60 days of the award, if applicable. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

- Indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity using the PHS Inclusion Enrollment Report, which is a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. For phase 3 clinical trials, use the form to describe plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity as appropriate for the scientific goals of the study.

  Statistical Plan and Data Analysis: Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

- **Attachment 9: Data Management (no page limit): Upload as "Data_Manage.pdf"** ***(only required for applications in which a clinical trial is proposed)*****.** The Data Management attachment should include the components listed below.

  Data Management: Describe all methods used for data collection, including the following:

  - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.

  - **Confidentiality**

    - Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.

    - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DOD are eligible to review study records.

    - Address requirements for reporting sensitive information to state or local authorities.

- **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe the database lock process. For FDA-regulated studies, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) are required.

- **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA (or appropriate international regulatory agency), if applicable.

- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

Laboratory Evaluations

- **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.

- **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).

- **Storage:** Describe specimen storage, including location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to store specimens for future use, including considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.

- **Labs performing evaluations and special precautions:** Identify the laboratory performing each evaluation, the applicable quality standard, and any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.

- **Attachment 10: Regulatory Strategy (no page limit)** ***(only required for applications in which a clinical trial is proposed)*****.** If submitting multiple documents, start each document on a new page. **Combine and upload as a single file named "Regulatory.pdf".** Describe the regulatory strategy using the following outline and provide supporting documentation as applicable.

State the product/intervention name.

State how many months into the award the anticipated clinical trial would be initiated after the award begins, taking into account any required advanced preclinical work (e.g., Good Manufacturing Practice (GMP) production, pharmacokinetics, and toxicity testing) and/or clinical trial preparation (IRB and DOD Human Research Protection Official approval).

For products/interventions that do not require regulation by the FDA or an international regulatory agency:

Explain why the product/intervention is exempt from oversight. Provide confirmation that the trial does not require regulation by the FDA/regulatory agency in writing from the IRB of record or the FDA/regulatory agency. No further information for this Attachment is required.

For products/interventions that require regulation by the FDA or an international regulatory agency:

State whether the product is FDA-approved, -licensed, or -cleared and marketed in the U.S.

If the product/intervention has already received FDA approval:

- Provide a copy of the acceptance letter from the FDA.
- If the product is marketed in the U.S., state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).

If the product/intervention has not already received FDA approval:

- State the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification.
- Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.
- Describe the overall regulatory strategy and product development plan that will support the planned product indication. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, and the types of FDA meetings that will be held/planned. Include considerations for

compliance with current GMP, Good Laboratory Practice (GLP), and Good Clinical Practice guidelines.

- If the clinical trial involves the use of a drug that has not been approved by the FDA for the proposed investigational use, then an IND application to the FDA that meets all requirements under 21 CFR 312 may be required and must be submitted to the FDA by the application submission deadline. If the investigational product is a device, evidence that an IDE application that meets all requirements under 21 CFR 812 has been submitted to the FDA by the application submission deadline, or that the device is exempt or qualifies for an abbreviated IDE is required. The Government reserves the right to withhold or withdraw funding if an IND or IDE is necessary but has not been submitted to the FDA by the application submission deadline, or if documented status of the IND or IDE has not been obtained within 9 months of the award date.

- If a drug is to be used in the proposed clinical trial, describe the current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support phase 1 testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).

- If a device is to be used in the proposed clinical trial, indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for the conduct of the clinical trial.

- **Attachment 11: Representations *(Extramural Submissions Only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.

- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in the performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form," available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under Subaward Costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".
- **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".
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.

- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

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

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 12.

II.D.2.b.iii. Full Application Submission Components for each Partnering PI

The application submission process for each Partnering PI uses an abbreviated full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(a), for detailed information.

(b) Attachments:

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.

- **Attachment 11: Representations *(Extramural submissions only)*: Upload as "RequiredReps.pdf".**

- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed information.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed information.

- **PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".

- **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".

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

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed information.

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

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

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to General Application Instructions, Section V.A.(f), for detailed information.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.

- **Intramural DOD Subaward:** Complete the "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov as Attachment 12.

II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, 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. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. 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 full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

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

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/content/home) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

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.

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

II.D.5. Funding Restrictions

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

II.D.5.a. Application Submissions with a Single PI

The application's total costs budgeted for the entire period of performance should not exceed **$2.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the 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.

II.D.5.b. Application Submissions with the Partnering PI Option

The combined total costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **$2.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

Any application that requests the higher level of funding and that does not include a collaborative PI will have its budget reduced as appropriate.

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

- Travel in support of multi-institutional collaborations.
- Costs for Initiating and Partnering PI(s) to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the PRP IIRA.

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, 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 individually evaluated according to the following **scored criteria**, which are of equal importance:

- **Research Strategy**
    - How well the preliminary and/ or published data, relevant literature, and scientific rationale support the proposed research project.
    - How well each 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.
    - How well the statistical plan is designed for the proposed research.
    - To what extent the proposed research project is feasible as described.
    - How well the application identifies potential problems and addresses alternative approaches.
    - For applications proposing prospective accrual of human subjects, the extent to which the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.

For applications with a clinical trial, the following additional **Clinical Strategy** review criteria will be evaluated:

- **Clinical Strategy**
    - How well the clinical trial portion of the application is designed with appropriate study variables, controls, endpoints, and data analysis plan.
    - If applicable, whether included biomarkers are specific to the intervention and demonstrate potential to improve patient selection, efficiency, and interpretation as well as potential to de-risk and improve design of anticipated later stage trials.

- How well the application demonstrates access to the study population, and ability to achieve recruitment goals.

- Whether the strategy for the inclusion of women and minorities and the distribution of proposed enrollment are appropriate for the proposed research, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects.

- Whether an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity is appropriate.

- For phase 3 clinical trials, whether the application describes plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity that are appropriate for the scientific goals of the study.

- **Impact**

  - How the proposed research will contribute to making an impact for individuals with or at risk for PD.

  - To what degree the proposed research, whether in the short term or long term, would make a major impact toward the PRP's mission of supporting Parkinson's research and/or patient care.

  - How well the proposed research addresses one or more of the FY24 PRP Focus Areas.

- **Principal Investigator and Research Team**

  - To what degree the PI's and other team members' experience, expertise, and record of accomplishment demonstrate their ability to successfully complete the proposed research project.

  - To what extent the levels of effort by the PI and other key personnel are appropriate to ensuring success of the proposed research project.

  - Whether the application proposes at least 15% dedication of full-time professional effort of the PI to this award.

  - If applicable, how well the clinical team possesses the appropriate expertise in PD and in conducting clinical trials?

  - **Partnering PI Option:**

    - How well do the partners bring different strengths to the application.

    - To what extent will their combined expertise better address the research question.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Budget**
    - Whether the budget is appropriate for the proposed research.
- **Environment**
    - To what extent the scientific environment is appropriate for the proposed research project.
    - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
    - To what extent the quality and level of institutional support are appropriate for the proposed research project.
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the Defense Health Program and FY24 PRP, as evidenced by the following:
    - Adherence to the intent of the funding opportunity
    - Program portfolio balance
    - Programmatic relevance to FY24 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**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for

programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the PRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. No commitment on the part of the government should be inferred from discussions with any other individual. ***The award document signed by the Grants Officer is the official authorizing document (i.e., assistance agreement).***

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to ***intragovernmental and intramural DOD organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP-issued awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis.

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

The organizational transfer of an award supporting a clinical trial is strongly discouraged and, in most cases, will not be allowed. Approval of a transfer request will be on a case-by-case basis 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 7, Section F, for general information on organization or PI changes.

II.F.3. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

Refer to the General Application Instructions, Appendix 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions for further information.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

Funded trials are required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Funded studies are required to register the study in the National Institutes of Health clinical trial registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

II.F.4. Reporting

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report.

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

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

Inclusion Enrollment Reporting: ***(only required for** clinical research **studies and pilot** clinical trials**)***: Enrollment reporting on the basis of sex/gender, race, and/or ethnicity using the PHS

Inclusion Enrollment Report will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission:

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace:

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

Email: support@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 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

After receipt of full applications, the following administrative actions may occur.

II.H.2.a. Rejection

The following will result in administrative rejection of the full application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- More than two applications are received naming the same investigator as the PI. Only the first two applications received will be accepted; additional applications will be administratively rejected.
- ***For clinical trials:*** Clinical Strategy Statement is missing (Attachment 8).
- ***For clinical trials:*** Data Management is missing (Attachment 9).
- ***For clinical trials:*** Regulatory Strategy is missing (Attachment 10).

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 full application:

- An FY24 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, including letters of support/recommendation. ***A list of the FY24 PRP Programmatic Panel members can be found at https://cdmrp.health.mil/prp/panels/panels24***.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.

- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if: (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds, and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The application does not address at least one of the FY24 PRP Focus Areas.

- The PI does not meet the eligibility criteria.

- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded	
	PI/Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐	☐
Summary and Application Contacts *(Intramural submissions only)*	☐	☐
Attachments		
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐	
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐	
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐	
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐	
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐	
Research Team Statement – Attachment 7, upload as "Team.pdf"	☐	
Clinical Strategy Statement – Attachment 8, upload as "Clinical.pdf"	☐	
Data Management – Attachment 9, upload as "Data_Manage.pdf"	☐	
Regulatory Strategy ***(****Only required for applications in which a clinical trial is proposed****)*** – Attachment 10, upload as "Regulatory.pdf"	☐	
Representations *(Extramural submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental Budget Form *(if applicable)* – Attachment 12, upload as "IGBudget.pdf"	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐	☐

Budget *(Intramural submissions only)* Include budget justification	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IIRA	Investigator-Initiated Research Award
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
PD	Parkinson's Disease
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PRP	Parkinson's Research Program
SAM	System for Award Management
SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs