Program Announcement

Department of Defense (DOD) Congressionally Directed Medical Research Programs

Peer Reviewed Cancer Research Program (PRCRP)

Synergistic Idea Award for Pediatric Brain Tumor Research only

Funding Opportunity Number: W81XWH-09-PRCRP-SIA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Peer Reviewed Cancer Research Program (PRCRP) is new for fiscal year 2009 (FY09). Congress appropriated funds for research into cancers not addressed by the Breast Cancer Research Program (BCRP), the Prostate Cancer Research Program (PCRP), or the Ovarian Cancer Research Program (OCRP), which are executed and managed by the Congressionally Directed Medical Research Programs (CDMRP). The total FY09 appropriation for the PRCRP is \$16 million (M).

The goal of the PRCRP is to improve quality of life by significantly decreasing the impact of cancer on service members, their families and the American public. The PRCRP fosters groundbreaking research, team science, and partnerships for the development of better prevention against, earlier detection of, and more effective treatments for cancer. PRCRP funds appropriated by Congress are directed for research in the following areas:

- \$4M for research of melanoma and other skin cancers as related to deployments of service members to areas of high exposure;
- \$2M for research of pediatric brain tumors within the field of childhood cancer;
- \$8M for genetic cancer research and its relation to exposure to the various environments that are unique to a military lifestyle;
- \$2M for non-invasive cancer ablation treatment research including selective targeting with nanoparticles.

B. Award Description

Applications for the FY09 PRCRP Synergistic Idea Award *must* address pediatric brain tumors within the field of childhood cancer. *No other topic areas should be addressed in this funding opportunity.* Within the field of pediatric brain tumor studies, the study of rare pediatric brain tumors is especially encouraged. Studies should include comprehensive methods for tumor data collection and host data collection.

The FY09 PRCRP Focus Areas for Pediatric Brain Tumors within the field of childhood cancer are as follows:

- Determining the differentiation of drivers between tumors and normal brain development
- Developing novel tools and models for narrowing the gaps in understanding genetic disposition, tumor initiation, and environmental factors
- Understanding the risks of therapeutic interventions to the host, and how these relate to long-term outcomes

The PRCRP seeks applications from all areas of basic, preclinical, behavioral, and epidemiological research, which should be responsive to one or more of the FY09 PRCRP Focus Areas.

The Synergistic Idea Award supports innovative approaches to pediatric brain tumor research involving two to four independent, faculty-level (or equivalent) Principal Investigators (PIs). These investigators should use synergistic and complementary perspectives to address a central problem or question in pediatric brain tumor research. *This award is designed to encourage and support both new and pre-existing partnerships*. The overall goal of this award is to accelerate advances in pediatric brain tumor research to support the PRCRP vision of reducing the impact of pediatric brain tumors on individuals living with the disease and their families.

The Synergistic Idea Award requires that investigators jointly design a single project. However, each partner will be recognized as a PI, must submit a separate application, and will receive an individual award. The research project must be supported by the unique expertise of each PI, and it must clearly define the synergistic components that will facilitate and accelerate progress in a way that could not be accomplished through independent efforts. *Multidisciplinary projects and multi-institutional projects are highly encouraged*. Each proposed study must include clearly stated plans for interactions among all PIs and institutions involved. The plans must include ongoing communication, coordination of research progress and results, and data transfer. Additionally, multi-institutional applications must provide an intellectual property plan to resolve potential intellectual and material property issues, and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of this award.

It is the responsibility of the PIs to clearly and explicitly articulate how the project addresses the following important aspects of the Synergistic Idea Award:

- **1. Synergy:** Synergy is a significant feature of this mechanism. These awards should accelerate research progress through ongoing communication and problem solving that approach the research problem from a variety of perspectives. The combined efforts of the PIs should result in a level of productivity that is greater than that achievable by each PI working independently. It should be clear that all PIs have an equal level of intellectual input into the proposed project. Contributions to the project are expected to be balanced between all PIs unless otherwise justified.
- **2. Innovation:** Innovative research may represent a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. This may include high-risk approaches to pediatric brain tumor research provided there is potential for significant impact. Research that is an incremental advance upon published data is not considered innovative and will not be considered for funding under this award mechanism.
- **3. Impact:** Research that has high impact will, if successful, significantly advance current methods and concepts for the prevention, detection, diagnosis, or treatment of pediatric brain tumor in humans. *Correlative clinical research studies are allowed under this mechanism. Clinical Trials are not permitted under this mechanism. For the*

definition of a Clinical Trial, refer to the Application Instructions and General Information, Appendix 6.

- **4. Responsiveness to Focus Areas**: The relevance of the research problem to one or more of the Focus Areas.
- 5. Preliminary data: Submission of preliminary data relevant to pediatric brain tumors and the proposed project is not required. If preliminary data is provided, it should be from the laboratory of the Initiating PI or Partnering PI(s). Although groundbreaking research often involves a degree of risk due to unforeseen difficulties or results, applications should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature.
- **6. PI Experience:** This award mechanism is designed to accommodate multiple PIs. Therefore, each PI must demonstrate that he or she possesses the research experience and resources to function as a PI in a synergistic project among equals, as well as an appropriate level of authority and responsibility to direct the project supported by the grant.

C. Eligibility

The Synergistic Idea Award requires the input of two to four independent investigators at or above the level of an Assistant Professor (or equivalent).

Refer to the Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **3** years.
- The maximum combined allowable funding for one collaborative partnership for the entire period of performance, regardless of whether there are two, three, or four PIs, is \$1,750,000 including direct and indirect costs. The maximum allowable funding is to be divided between the PIs of each collaborative partnership.
- The applicants may request the entire maximum direct cost amount for a project that may be less than the maximum 3-year period of performance.
- Regardless of the period of performance proposed, the budget may not exceed the maximum combined direct and indirect costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement.

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

Within the guidelines provided in the Application Instructions and General Information, funds can cover:

- Salary
- Research supplies

- Equipment
- Clinical research costs

Correlative clinical research studies <u>are allowed</u> under this mechanism. Clinical Trials are <u>not permitted</u> under this mechanism. For the definition of a Clinical Trial, refer to the Application Instructions and General Information, Appendix 6.

- Travel to scientific/technical meetings
- Travel between collaborating institutions

The CDMRP expects to allot \$1.75M of the \$16M FY09 PRCRP appropriation to fund approximately 1 Synergistic Idea Award in Pediatric Brain Tumor collaborative partnership (representing 2-4 individual awards). Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

E. Award Administration

Changes in Initiating or Partnering PIs will not be allowed for the Synergistic Idea Award except under extreme circumstances, which will be evaluated on a case-by-case basis and at the discretion of the Grants Officer, provided that the intent of the award mechanism is met.

Refer to the Application Instructions and General Instructions, Appendix 5, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) an application submission. *Pre-application submission is a required first step*.

• Pre-application Submission Deadline: August 5, 2009, 5:00 p.m. Eastern time (ET)

• Invitation to Submit a Proposal: October 19, 2009

• Application Submission Deadline: December 9, 2009, 11:59 p.m. ET

Scientific Peer Review: January 2010
 Programmatic Review: March 2010

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

III. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the <u>CDMRP eReceipt system (https://cdmrp.org/)</u> and (2) an application submission through <u>Grants.gov (http://www.grants.gov/)</u>. A letter of invitation is mandatory for submission of an application. Applications will be invited based on pre-application screening.

The Synergistic Idea Award mechanism is structured to accommodate two to four PIs. Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute equally to the preparation of the application. The Initiating PI must complete the preapplication submission process and submit the contact information for all of the Partnering PI(s). If an application is invited, the Initiating PI will receive a letter of invitation via email by the CDMRP eReceipt system. The letter will provide the information necessary to begin the application submission through Grants.gov. The Partnering PI(s) will subsequently be notified separately by email. Please note that all of the Partnering PI(s) must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI.

Failure by the Initiating PI or any Partnering PI to submit his or her required application components will result in administrative rejection of all applications associated with the proposed research project.

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative applications.

A. Step 1 – Pre-Application Components and Submission

The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the <u>CDMRP eReceipt system</u> by 5:00 p.m. ET on the pre-application deadline.

Pre-application submission is a required first step. The PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. The Initiating and Partnering PIs will each be assigned unique and separate log numbers by the CDMRP eReceipt system. Each PI must submit his/her Grants.gov application package using only his/her unique log number. If there is a change in PI or organization after the submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507. In addition to the award-specific instructions below, refer to the Application Instructions for detailed information on pre-application components and submission. **The Initiating PI is responsible for submission of all pre-application components.**

- **Proposal Information:** The Initiating PI must enter the Application Information before continuing the pre-application.
- **Proposal Contacts:** The Initiating PI must enter his/her contact information.
- Collaborators and Conflicts of Interest (COI): The Initiating PI must enter the contact information for the Partnering PI(s) in the Partnering PI(s) section to indicate his/her role in the project. In addition, any other persons who should be excluded from review of the application should be named.
- **Preproposal Narrative:** The Preproposal Narrative has a **three-page limit** inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures,

pictorials, cartoons, and other information needed to judge the preproposal. The Preproposal Narrative should address the following:

- o **Rationale:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations.
- Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.
- Research Aims: Concisely describe the project's specific aims. Correlative clinical research studies are allowed under this mechanism. Clinical Trials are not permitted under this mechanism. For the definition of a Clinical Trial, refer to the Application Instructions and General Information, Appendix 6.
- o **Synergy:** Describe how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently and that is centered on a unified objective.
- o **Innovation:** Describe how the proposed study is innovative.
- o **Impact:** Describe the potential impact of this study on pediatric brain tumors and how it may significantly accelerate the eradication of the disease and/or improve patient care.
- Focus Areas: Describe how the proposed study is responsive to one or more of the FY09 Focus Areas for pediatric brain tumors within the field of childhood cancer research.
- Pre-Application Supporting Documentation: Journal references, one-page.

Pre-Application Screening: Pre-applications will be screened by the FY09 PRCRP Integration Panel based on the following criteria:

- 1. Synergy: How well the proposed study represents a synergistic collaboration.
- **2. Innovation:** How well the proposed research represents more than the next logical step or an incremental advance upon published data.
- **3. Impact:** To what degree the proposed study makes an important contribution that significantly advances the prevention, detection, diagnosis, and/or treatment of pediatric brain tumors.
- **4. Responsiveness to Intent:** How well the proposed research addresses one or more of the FY09 Focus Areas for pediatric brain tumors within the field of childhood cancer research.

B. Step 2 – Application Components and Submission

Principal Investigators will receive notification of invitation to submit an application for the Synergistic Idea Award. Application submissions will not be accepted unless the PI has been invited. Do not submit an application unless the Initiating and Partnering PIs receive a letter of invitation. If invited to submit an application, the Partnering PIs will be contacted via email by the CDMRP eReceipt system and provided the information necessary to begin application submission through Grants.gov. Please note that the Partnering PIs must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI.

Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov). No paper copies will be accepted.

Each application submission must include the completed Grants.gov application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title, research objectives, or focus area(s).

The CDMRP requires separate Grants.gov application package submissions for Initiating and Partnering PIs. The Initiating and Partnering PIs will each be assigned unique and separate log numbers by the CDMRP eReceipt system. Each PI must submit his/her Grants.gov application package using only his/her unique log number. Each PI must also submit an identical copy of a joint Statement of Work (SOW).

Failure by the Initiating PI or any Partnering PI to submit his or her required application components will result in administrative rejection of all applications associated with the proposed research project.

APPLICATION COMPONENTS AND SUBMISSION FOR THE INITIATING PI

The Initiating PI package includes:

- 1. SF-424 (R&R) Application for Federal Assistance Form
- 2. Attachments Form
 - Attachment 1: Project Narrative (10-page limit)

Describe the proposed research in detail using the following outline. The inclusion of preliminary data relevant to pediatric brain tumors and the proposed project is not required. Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.

Background: Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application. Describe each PI's history of synergistic and collaborative study with one another and/or with other investigators.

Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.

Specific Aims: Concisely explain the project's specific aims. If this application is part of a larger study, present only tasks that the DOD award would fund.

Research Strategy: Describe the experimental design, methods, and analyses, including appropriate controls in sufficient detail for analysis. Include specific examples of synergistic elements incorporated into the research design. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Studies should include comprehensive methods for tumor data collection and host data collection. Correlative clinical research studies are allowed under this mechanism. Clinical Trials are not permitted under this mechanism. For the definition of a Clinical Trial, refer to the Application Instructions and General Information, Appendix 6.

Project Coordination and Communication: Describe plans for ongoing communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all PIs and institutions participating in the project.

• Attachment 2: Supporting Documentation

- References Cited
- Acronyms and Symbol Definitions
- o Facilities & Other Resources
- Description of Existing Equipment
- Publications and/or Patent Abstracts (five-document limit)
- Letters of Institutional Support
- Letters of Collaboration (if applicable)
- o Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical Abstract
- Attachment 4: Public Abstract
- Attachment 5: Statement of Work (SOW; three-page limit)
- Attachment 6: Detailed Budget and Justification

• Attachment 7: Impact Statement (one-page limit)

State explicitly how the proposed work will, if successful, have an impact on human pediatric brain tumors and how the expected results of the project will contribute to the goals of improving quality of life by significantly decreasing the impact of pediatric brain tumors on patients and their families by fostering groundbreaking research on the prevention, detection, diagnosis, or treatment of the disease.

• Attachment 8: Innovation Statement (one-page limit)

Summarize how the proposed work is innovative. Investigating the next logical step or an incremental advancement on published data is *not* considered innovative.

Although not all inclusive, the following examples are ways in which proposed work may be innovative, and are intended to help PIs frame the innovative features:

- o Study concept Investigation of a novel idea and/or research question
- o Research method or technology Use of novel research methods or new technologies, including technology development, to address a research question
- Novel method or technology Development of a novel method or technology for prevention, detection, diagnosis, or treatment
- Existing methods or technologies Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended

• Attachment 9: Synergy Statement (one-page limit)

Discuss, in detail, the advantages of addressing this problem through the combined expertise of the PIs and how this contributes to the synergy of the application. Describe the elements of interdependence in the proposed work and the contributions of each PI to the overall synergy of the project. Describe how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently.

• Attachment 10: Federal Financial Plan (if applicable). No page limit, named "FedFin.pdf." Proposals from Federal agencies must provide a plan delineating how all funds will be obligated by September 30, 2010, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as through agreements with foundations, non-Federal institutions, and universities. It should be noted, however, that it is contrary to policy to allow for any Recipient to send funds back to a U.S. Government entity except under very limited circumstances provided for in USAMRAA policy, such as:

- (1) The Recipient can show that such funds will not originate from the USAMRMC award, or
- (2) There is separate statutory authority, aside from Cooperative Research and Development Agreement (CRADA) authority, that would allow for it, or
- (3) The Recipient can show that exceptional or extraordinary circumstances exist that merit a waiver of this policy.

Such waiver must receive approval from the USAMRMC Resource Management Office and the Staff Judge Advocate before approval by USAMRAA. Examples of exceptional circumstances that could merit approval would be (i) if the research protocol involved numerous radiological studies, such as computer tomography scans, which needed to be performed and analyzed at a U.S. Government medical treatment facility (MTF) after the normal expiration of the Appropriation from which the award was made, and which studies would otherwise not be performed as part of the standard of medical care, and/or (ii) if the research calls for the purchase and use of chemical or biological materials that cannot legally be purchased and/or used by the Recipient but can legally be purchased by the Government lab or MTF, then a CRADA can be employed for the Recipient to provide those funds to the lab or MTF to make such purchases.

Recipients under a cooperative agreement are allowed to provide non-fund resources to a Government lab or MTF, such as supplies, equipment, or personnel. This should be specifically provided for under the assistance document.

• Attachments 11-15: Subaward Detailed Budget and Justification (if applicable)

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

- PI Biographical Sketch
- PI Current/Pending Support
- Key Personnel Biographical Sketches
- Include the Partnering PIs
- Key Personnel Current/Pending Support
- Include the Partnering PIs

4. Research & Related Project/Performance Site Location(s) Form

APPLICATION COMPONENTS AND SUBMISSION FOR THE PARTNERING PI(S)

The Partnering PI(s) must follow the link in the email from CDMRP eReceipt and complete the registration process prior to the application submission deadline in order to associate their grant application package with that of the Initiating PI.

The Initiating and Partnering PIs will each be assigned unique and separate log numbers by the CDMRP eReceipt system. Each PI must submit his/her Grants.gov application package using only his/her unique log number. Each PI must also submit an identical copy of a joint Statement of Work (SOW).

The application submission process for the Partnering PI(s) uses an abbreviated application package of forms and attachments from Grants.gov.

The Partnering PI package includes:

1. SF-424 (R&R) Application for Federal Assistance Form

2. Attachments Form

- Attachment 5: SOW (3 page limit)
- Attachment 6: Detailed Budget and Justification
- Attachment 10: Federal Financial Plan (if applicable). No page limit, named "FedFin.pdf." Proposals from Federal agencies must provide a plan delineating how all funds will be obligated by September 30, 2010, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as through agreements with foundations, non-Federal institutions, and universities. It should be noted, however, that it is contrary to policy to allow for any Recipient to send funds back to a U.S. Government entity except under very limited circumstances provided for in USAMRAA policy, such as:
 - (1) The Recipient can show that such funds will not originate from the USAMRMC award, or
 - (2) There is separate statutory authority, aside from Cooperative Research and Development Agreement (CRADA) authority, that would allow for it, or
 - (3) The Recipient can show that exceptional or extraordinary circumstances exist that merit a waiver of this policy.

Such waiver must receive approval from the USAMRMC Resource Management Office and the Staff Judge Advocate before approval by USAMRAA. Examples of exceptional circumstances that could merit approval would be (i) if the research protocol involved numerous radiological studies, such as computer tomography scans, which needed to be performed and analyzed at a U.S. Government medical treatment (MTF) facility after the normal expiration of the Appropriation from which the award was made, and which studies would otherwise not be performed as part of the standard of medical care, and/or (ii) if the research calls for the purchase and use of chemical or biological materials that cannot legally be purchased and/or used by the Recipient but can legally be purchased by the Government lab or MTF, then a CRADA can be employed for the Recipient to provide those funds to the lab or MTF to make such purchases.

Recipients under a cooperative agreement are allowed to provide non-fund resources to a Government lab or MTF, such as supplies, equipment, or personnel. This should be specifically provided for under the assistance document.

- Attachments 11-15: Subaward Detailed Budget and Justification (if applicable)
- 3. Research & Related Project/Performance Site Location(s) Form

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit, the overall goals of the program, and the specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at http://cdmrp.army.mil/fundingprocess.htm.

The peer review and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other correcting actions. Correspondingly, institutional personnel and PIs are prohibited from contacting persons involved in the application 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 institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 Unites States Code 1905).

The Government reserves the right to review all applications based on one or more of the required attachments or supporting documentation (e.g., Impact Statement, Innovation Statement, or Synergy Statement).

B. Review Criteria

- **1. Peer Review:** All applications will be evaluated according to the following criteria. Of these, Synergy, Innovation, and Impact are equally the most important, with the remaining criteria listed in decreasing order of importance.
 - Synergy

- How the proposed partnership between independent PIs is likely to result in a level of productivity that is greater than that achievable by each PI working independently.
- o How well the application outlines the balanced contributions of each PI to the overall synergy of the project.
- o How the proposed project is centered on a unified theme that addresses a single research question rather than an additive set of unrelated subprojects.
- How well the application addresses processes for ongoing communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all participating PIs and institutions.

Innovation

- o How well the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
- How the proposed research represents more than an incremental advance upon published data.

• Impact

- o How the project will expand knowledge of specific pediatric brain tumors beyond other existing collaborative studies.
- How the project, if successful, will make an original and significant contribution to the goals of improving quality of life by significantly decreasing the impact of pediatric brain tumors on patients and their families by fostering groundbreaking research on the prevention, detection, diagnosis, or treatment of the disease.

• Responsiveness to Focus Areas

 How well the proposed research project responds to one or more the FY09 PRCRP for pediatric brain tumor research Focus Areas, toward the goal of advancing pediatric brain tumor research.

• Research Strategy and Feasibility

- How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, pediatric brain tumor-relevant preliminary data, and/or logical reasoning.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
- How well the PIs acknowledge potential problems and address alternative approaches.

Personnel

- The degree to which each PI possesses the research experience to function as a PI in a synergistic project.
- o How the research team's background and pediatric brain tumor-related expertise are appropriate with respect to its ability to perform the proposed work.
- o To what degree the levels of effort are appropriate for successful conduct of the proposed work.

The following criteria will not be individually scored, but may impact the overall evaluation of the application.

Environment

- o How the scientific environment is appropriate for the proposed research.
- o How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- How the quality and extent of institutional support are appropriate.

Budget

- o How the budgets are appropriate for the proposed research and within the limitations of the award mechanism.
- o Whether the resources are divided appropriately among all PIs.

• Application Presentation

- o How the writing and components of the application influenced the review.
- **2. Programmatic** Review: Criteria used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio include:
 - Adherence to the intent of the award mechanism
 - Programmatic relevance
 - Ratings and evaluations of the peer reviewers
 - Relative synergy, innovation, impact, and responsiveness to FY09 PRCRP pediatric brain tumor research Focus Areas
 - Program portfolio balance

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel members and recommended for funding to the Commanding General, USAMRMC.

V. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of all applications associated with the proposed research project:

- Initiating or Partnering PI(s) application is missing.
- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Initiating or Partnering PI(s) budget is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following the application deadline you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- Any FY09 IP member is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY09 IP members may be found at http://cdmrp.army.mil/09prcrppanel.htm.
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.

- The application does not conform to this funding opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed maximum allowed by the award mechanism.
- Inclusion of URLs with the exception of links to published references.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to provide the findings of the investigation to the USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

1. Program Announcement/Funding Opportunity, application format, or required documentation: To view all Program Announcements/Funding Opportunities offered by the CDMRP, perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079

Fax: 301-619-7792

Email: cdmrp.pa@amedd.army.mil

2. eReceipt system: Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507
Website: https://cdmrp.org
Email: help@cdmrp.org

3. Grants.gov contacts: Questions related to application submission through the <u>Grants.gov</u> (http://www.grants.gov/) portal should be directed to Grants.gov help desk, which is available Monday through Friday from 7:00 a.m. to 9:00 p.m ET. The deadline for application submission is 11:59 p.m. ET on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov help desk will be unavailable. Please note that the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726

Email: <u>support@grants.gov</u>

Grants.gov will notify Principal Investigators (PIs) of changes made to this Program Announcement/Funding Opportunity and/or application package ONLY if the PI subscribes to the mailing list by clicking on the "send me change notification emails" link on the Opportunity Synopsis page for this announcement. If the PI does not subscribe and the application package is updated or changed, the original version of the application package may not be accepted.