

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Glioblastoma Research Program

Hypothesis Development Award

Announcement Type: Initial

Funding Opportunity Number: HT942524GBMRPHDA

**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), November 6, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, November 20, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, November 25, 2024
- **Peer Review:** January 2025
- **Programmatic Review:** March 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) Glioblastoma Research Program (GBMRP) 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. Congress initiated the GBMRP in 2024 with an appropriation of \$10M.

The vision of the GBMRP is to improve glioblastoma patient survival and reduce adverse impact on Service Members, Veterans, their Families, and the American public. The mission is to promote rigorous, high-impact research to drive scientific discovery and advances in diagnosis, treatment, and quality of life for patients with glioblastoma. The FY24 GBMRP challenges the scientific community to design innovative research that fosters new directions or addresses neglected issues in the field to advance the development of health care solutions for individuals affected with glioblastoma.

In 2021, the World Health Organization (WHO) published the fifth edition of the Classification of Tumours of the Central Nervous System.¹ The new classification characterizes glioblastoma as isocitrate dehydrogenase (IDH)-wild type, isolating IDH-mutant forms into other entities. The GBMRP will be following the WHO 2021 classification and **applications must propose research focused on glioblastoma IDH-wild type.**

II.A.1. FY24 GBMRP Hypothesis Development Award Focus Areas

To meet the intent of the funding opportunity applications **must** address at least one of the FY24 GBMRP Hypothesis Development Award focus areas:

Drug Delivery: Identification and development of strategies and technologies for increased therapeutic efficacy and reduced toxicity. Examples include chemical, molecular, or mechanical delivery approaches aimed at overcoming the blood-brain barrier and increasing therapeutic access to the central nervous system.

Biomarkers: Identification and development of promising biomarkers for glioblastoma. Biomarkers may include, but are not limited to, susceptibility/risk, diagnostic, prognostic, monitoring, predictive, therapeutic response, or safety biomarkers.² Noninvasive or minimally invasive strategies and technologies (imaging approaches, genetic and epigenetic stratification/characterization, radiomics, etc.) are particularly encouraged.

¹ Louis DN, Ohgaki H, Wiestler OD, et al. 2007. The 2007 WHO Classification of Tumours of the Central Nervous System. *Acta Neuropathol* 114:97-109. <https://doi.org/10.1007/s00401-007-0243-4>

² Califf RM. 2018. Biomarker definitions and their applications. *Exp Biol Med* (Maywood) 243(3):213-221. <https://doi.org/10.1177/1535370217750088>

II.B. Award Information

The FY24 GBMRP Hypothesis Development Award supports the exploration of highly innovative, untested, exploratory, high-risk/potentially high-gain concepts, theories, paradigms, and/or methods that address an important problem relevant to one or more of the [FY24 GBMRP Hypothesis Development Award Focus Areas](#).

This award is designed to provide investigators the opportunity to pursue serendipitous observations that may reveal entirely new avenues for investigation. Results of studies conducted through this award may provide the scientific premise upon which a new hypothesis can be based or initial proof-of-principle of an innovative hypothesis, laying the groundwork for future glioblastoma-focused research projects.

The GBMRP encourages applications from early-career investigators and applications that include meaningful and productive collaborations between investigators. PIs with little to no previous glioblastoma experience are encouraged to collaborate with experienced glioblastoma researchers and/or clinicians.

Key Aspects of the Hypothesis Development Award:

Presentation of preliminary data is inconsistent with the intent of this award mechanism and is therefore strongly discouraged. However, proposals should be based on sound scientific rationale that is established through logical reasoning and critical review and analysis of the literature.

Innovation: It is the responsibility of the Principal Investigators (PIs) to clearly and explicitly articulate how the proposed research project meets the exploratory intent of this mechanism and is innovative in the field of glioblastoma research.

Impact: The PI(s) should articulate the short- and long-term impact of the proposed research on both the glioblastoma research field as well as the patient community. The anticipated impact must be significant and move beyond an incremental advancement.

Partnering Principal Investigator Option: The FY24 GBMRP Hypothesis Development Award 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 will be identified as the Partnering PI. **This funding opportunity allows one Partnering PI.** Both 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, refer to [Section II.D.2, Content and Form of the Application Submission](#).

Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers:

Clinical research is allowed.

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](#).

Clinical trials are NOT allowed.

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.

Other Important Considerations:

Preclinical Research: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (<https://www.nature.com/articles/nature11556>). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies.

Relevance to Military 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, their Families, and the American public. 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.

Organizational-Level Areas of Emphasis:

The following areas of emphasis are broadly applicable to many CDMRP programs, not just the GBMRP. They are areas of health and medicine identified as having knowledge gaps that need to be addressed. Investigators are encouraged to consider addressing these areas in their applications if doing so is appropriate for their line of research, addresses the [FY24 GBMRP Hypothesis Development Award Focus Areas](#), and meets the intent of the award mechanism.

Metastatic Cancer Task Force: A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations (<https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research>) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY24 GBMRP priorities.

Nuclear Medicine: 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.

Women's Health: CDMRP encourages research in 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.

Funding Details:

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

The anticipated direct costs budgeted for the entire period of performance for an FY24 GBMRP HDA should not exceed **\$200,000**. The anticipated direct costs budgeted for the entire period of performance for an FY24 GBMRP HDA with Partnering PI Option should not exceed **\$300,000**. 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 \$4.64M to fund approximately 13 Hypothesis Development Award 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 all levels are eligible to be named as PI.

Early-career investigators (defined as independent, non-mentored investigators at least 2 years beyond their last training position, e.g., postdoctoral fellowship, medical residency, clinical fellowship as of the application submission deadline) are encouraged to apply.

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

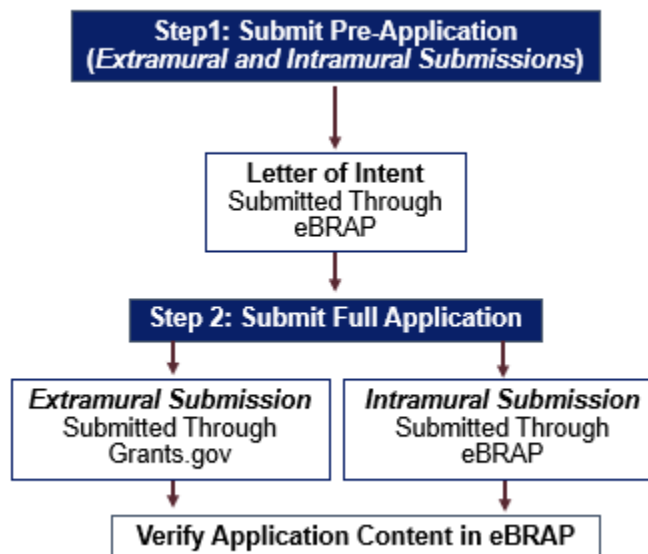
Submission is a two-step process requiring both a **pre-application** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a **full application** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission 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 HT942524GBMRPHDA 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 HT942524GBMRPHDA 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 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 GBMRP 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 the Partnering PI if exercising the Hypothesis Development Award – 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 will be notified of the pre-application submission via an email from eBRAP. The *Partnering PI 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 must register in eBRAP.

After associating the pre-application with their eBRAP account, the Partnering PI 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).

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

- The Partnering PI 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	Hypothesis Development Award
Initiating and Partnering PI	Hypothesis Development Award – 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 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 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 PI during pre-application submission. *All associated applications (the Initiating PI's and 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 (two-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.

- Describe how the project addresses an important problem relevant to one or more of the [FY24 GBMRP Hypothesis Development Award Focus Areas](#).
- **Rationale:** State the rationale for the proposed research. *The inclusion of preliminary data is strongly discouraged.* However, the study rationale should be based on sound scientific reasoning. This should include relevant literature citations and could be derived from studies of other cancer type(s)/subtype(s) or diseases with sufficient justification as to why this may be relevant to glioblastoma.
- **Hypothesis:** State the hypothesis to be tested.
- **Specific Aims:** State concisely the specific aims of the study.
- **Research Strategy and Feasibility:** Describe the experimental design, methodology, and analyses, including appropriate controls, in sufficient detail for

evaluation of their appropriateness and feasibility. Describe how the studies are designed to achieve the project aims. Describe how sex as a biological variable will be considered, including collection of data disaggregated by sex and a brief description of a sufficiently powered statistical analysis for sex differences. For [clinical research](#), see [Inclusion Enrollment Plan](#)-for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.

Clinical trials are not allowed.

- **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 (two-page limit per letter is recommended):** 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) (two-page limit per letter is recommended):** 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.
- **Intellectual Property:** Information can be found in the 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.
 - **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instructions 3200.12](#). ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.
 - **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, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's 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 CDMRP's expectations for making data and research resources publicly available.
 - **Inclusion Enrollment Plan (*only required if [clinical research](#) is proposed*):** 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 IRB review) are exempt from this requirement.
- **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.

- **Rationale:** State the [FY24 GBMRP Hypothesis Development Award Focus Area\(s\)](#) to be addressed. *Describe how the proposed research project directly addresses one or more of the focus areas.* Present the scientific rationale behind the proposed research project.
- **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached.
- **Specific Aims:** State the specific aims of the study.
- **Research Strategy and Feasibility:** Describe the study design, including appropriate controls.
- **Innovation:** Summarize how the proposed research project is innovative in the field of glioblastoma.
- **Impact:** Explain how the proposed project will make an important contribution toward advancing glioblastoma research, patient care, and/or quality of life.
- **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 of scientific jargon, acronyms, and abbreviations.

- State the [FY24 GBMRP Hypothesis Development Award Focus Area\(s\)](#) to be addressed by the research project.
- Summarize the aims, objectives, and rationale for the proposed research.
- Summarize how the proposed research is innovative and will lead to new avenues of discovery or development.
- Describe the applicability of the research to the glioblastoma community by considering the following:
 - How will the research outcomes benefit Service Members, Veterans, their Families, and the American public?
 - What are the potential applications, benefits, and risks of the anticipated outcomes?
 - Describe the short- and long-term goals that are related to patient care, outcomes, or quality of life. If the research is too basic for short-term clinical applicability, describe the interim research outcomes expected and their applicability to the field of glioblastoma. Basic research should have the long-term goal of advancing the glioblastoma field and/or impacting 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 Hypothesis Development Award, refer to the “Example: Assembling a Generic Statement of Work”, for guidance on preparing the SOW. Use the “Suggested SOW Format” to develop the SOW for the proposed research. Submit as a PDF.
- **Partnering PI Option:** Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and the Partnering PI(s) should be clearly noted for each task.
- **Attachment 6: Innovation Statement (one-page limit): Upload as “Innovation.pdf”.** Describe how the project will lead to a new paradigm, challenge current paradigms, look at existing problems from new perspectives, introduce novel concepts or agents, or exhibit other uniquely creative qualities. Justify how the proposed research represents

more than an incremental advancement, studies a new avenue of research for the laboratory, and/or addresses new concepts beyond already established lines of research in the PI's laboratory and/or published data.

- **Attachment 7: Impact Statement (one-page limit): Upload as “Impact.pdf”. Using language that is readily understood by readers without a background in science or medicine:**
 - **Focus Area(s):** Explain why the proposed research project is important and the impact it will have on one or more of the [FY24 GBMRP Hypothesis Development Award Focus Areas](#).
 - **Short-term impact:** Describe the anticipated outcome(s)/product(s) (short-term gains) from the proposed research and how they will help lay the groundwork for future avenues of scientific investigation and advance the state of the science/technology in glioblastoma.
 - **Long-term impact:** Explain how the anticipated long-term gains from the proposed research project may ultimately contribute to the goal of improving glioblastoma patient survival and reducing the adverse impact on Service Members, Veterans, their Families, and the American public. *All research, including basic, should relate to patient outcomes and how it benefits those affected by glioblastoma.*
- **Attachment 8: Partnership Statement (one-page limit), if applicable: Upload as “Partnership.pdf”. (Attachment 8 is only applicable and required for applications submitted under the Partnering PI option.)** If a Partnering PI project is proposed, the applicant must submit a summary of the structure and intent of the collaboration(s):
 - Describe the expertise and resources (physical and process resources or intellectual properties) that each PI will bring to the effort and how they are best suited to carry out the proposed research.
 - Describe the specific role(s) of each PI ensuring a substantial contribution by each Partner and the reciprocal flow of ideas and information.
 - Indicate how the partnership will enable a level of productivity greater than that achievable by each PI working independently.
- **Attachment 9: Animal Research Plan (one-page limit): Upload as “AnimalResPlan.pdf”. (Attachment 9 is only applicable and required for applications proposing animal studies.)**

If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the ARRIVE guidelines 2.0 (Animal Research: Reporting In Vivo Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at <https://arriveguidelines.org/arrive-guidelines>. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the

Institutional Animal Care and Use Committee. The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study’s relevance to human biology.
 - Summarize the procedures to be conducted. Describe how the study will be controlled.
 - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
 - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
 - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- **Attachment 10: 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 11: Suggested Intragovernmental/Intramural Budget Form (*if applicable*): Upload as “IGBudget.pdf”.** If an [intramural DOD organization](#) will be a collaborator in 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.
 - **Partnering PI Option:** *Initiating and Partnering PIs must have separate budgets 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 the Partnering 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 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 13.

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

The application submission process for the 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 10: Representations (*Extramural submissions only*)**: Upload as “RequiredReps.pdf”.
- **Attachment 11: Suggested Intragovernmental/Intramural Budget Form (*if applicable*)**: 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 PI and Partnering PI must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov 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 13.

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 **2** years.

Application submissions with a **Single PI**:

The application's direct costs budgeted for the entire period of performance should not exceed **\$200,000**.

Application submissions with the **Partnering PI Option**:

The applications' combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **\$300,000**.

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

The Initiating and Partnering 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.

All application submissions:

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(s) may request the entire maximum funding amount for a project that may have a period of performance of less than the maximum **2** years.

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

- Costs for one investigator 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 FY24 GBMRP Hypothesis Development Award.
- Travel in support of multi-institutional collaborations.

Must not be requested for:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.
- Costs to support clinical trials.

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:

- **Innovation**
 - To what degree the project will lead to a new paradigm, challenge current paradigms, look at existing problems from new perspectives, introduce novel concepts or agents, or exhibit other uniquely creative qualities.
 - To what degree the application indicates that the proposed research represents more than an incremental advance, studies a new avenue of research for the laboratory, and/or addresses new concepts beyond already established lines of research in the PI's laboratory and/or published data.
- **Impact**
 - How well the proposed research project addresses one or more of the [FY24 GBMRP Hypothesis Development Award Focus Areas](#).
 - **Assuming the objectives/goals of the proposed research project are realized:**
 - To what degree the anticipated outcome(s)/products(s) (short-term gains) of the project lay the groundwork for future avenues of scientific investigation and advance the state of the science/technology in glioblastoma.
 - To what degree the proposed research would contribute, in the long term, toward improving glioblastoma patient survival and reducing adverse impact on Service Members, Veterans, their Families, and the American public.
- **Research Strategy and Feasibility**
 - To what extent the scientific rationale supports the project, as demonstrated by a critical review and analysis of the literature and sound scientific reasoning. If preliminary data are presented, **which is discouraged**, whether they support the hypothesis or objective.
 - To what degree the hypothesis or objective, research strategy, methodology, and analyses are well-developed and appropriate to address the stated objectives and supporting the successful completion of the specific aims.

- If applicable, how well the animal studies are designed to achieve the research objectives, to include the use of appropriate models.
- How well sex as a biological variable is considered and how well analyses account for sex differences.
- If clinical research is proposed, whether the strategies for the inclusion of women and minorities are appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, ethnicity, and an accompanying rationale for the selection of subjects. Whether a completed Inclusion Enrollment Report providing anticipated enrollment table(s) for the inclusion of women and minorities is included with the application.
- **For applications submitted under the Partnering PI Option:**
 - Based on the Partnership Statement, how well the project incorporates the unique expertise and resources of each Partner and how the partnership is best suited to carry out the proposed research.
 - How the proposed partnership assures a substantial contribution by each Partner and the reciprocal flow of ideas and information.
 - Whether the proposed partnership will enable a level productivity greater than that achievable by each PI working independently.

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**:

- **Personnel**
 - Based on the information in the biographical sketches, to what degree the research team's background and expertise are appropriate to accomplish the proposed research.
 - Based on the budget justification, to what degree the levels of effort are appropriate to ensure successful conduct of the proposed work.
- **Budget**
 - Whether the budget is appropriate for the proposed research.
 - Whether the **direct costs** exceed the allowable direct costs as published in the program announcement.
- **Environment**
 - To what extent the scientific environment and level of institutional support is appropriate for the proposed research project.

- How well the research requirements are supported by the availability of and accessibility to facilities and resources.
- **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 GBMRP, as evidenced by the following:
 - Adherence to the intent of the funding opportunity
 - Program portfolio composition
 - Relative innovation and 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 GBMRP 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 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 and organizational transfer of an award supporting the Initiating PI or Partnering PI are discouraged and will be evaluated on a case-by-case basis.

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, Institutional Review Board, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

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 (RPPR).

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

PHS Inclusion Enrollment Reporting Requirement (only required for [clinical research studies](#)): Enrollment reporting on the basis of sex/gender, race, and/or ethnicity 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:

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

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 GBMRP 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 GBMRP Programmatic Panel members can be found at <https://cdmrp.health.mil/gbmrp/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 PI does not meet the eligibility criteria.
- Failure to submit all associated (Initiating and Partnering PIs') applications by the deadline.
- The main subject of the research is not glioblastoma IDH-wildtype.
- The application does not address at least one of the FY24 GBMRP Hypothesis Development Award Focus Areas in [Section II.A.1](#).
- A clinical trial is proposed.

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	
	Single PI or Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance (<i>Extramural submissions only</i>)	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) (<i>Intramural submissions only</i>)	☐	☐
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”	☐	☐
Innovation Statement – Attachment 6, upload as “Innovation.pdf”	☐	
Impact Statement – Attachment 7, upload as “Impact.pdf”	☐	
Partnership Statement – Attachment 8, upload as Partnership.pdf”	☐	
Animal Research Plan (<i>if applicable</i>) – Attachment 9, upload as “AnimalResPlan.pdf”	☐	
Representations (<i>Extramural submissions only</i>) – Attachment 10, upload as “RequiredReps.pdf”	☐	☐
Suggested Intragovernmental/Intramural Budget Form (<i>if applicable</i>) – Attachment 11, 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 (<i>Extramural submissions only</i>) Include budget justification	☐	☐

Full Application Components	Uploaded	
	Single PI or Initiating PI	Partnering PI
Budget (<i>Intramural submissions only</i>) Include budget justification	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form (<i>if applicable</i>)	☐	☐

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
FY	Fiscal Year
GBMRP	Glioblastoma Research Program
HDA	Hypothesis Development Award
IDH	Isocitrate Dehydrogenase
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
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
WHO	World Health Organization