I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Glioblastoma Research Program

Transformative Consortium Award

Announcement Type: Initial

Funding Opportunity Number: HT942524GBMRPTCA

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), December 23, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, January 13, 2025
- **End of Application Verification Period:** 5:00 p.m. ET, January 17, 2025
- **Peer Review:** February 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), "Research and Development Projects." 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 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 Areas of Emphasis

The mission of the GBMRP is to promote rigorous, high-impact research to drive scientific discovery and advances in diagnosis, treatment, and quality of life for patients with glioblastoma. Within this context, the GBMRP is interested in supporting collaborative research that addresses specific gaps in glioblastoma research and clinical care; therefore, applications ***must address one or more*** of the following FY24 GBMRP Areas of Emphasis:

- **Develop new treatments or advance existing therapies to improve outcomes for glioblastoma patients**

  Applications must propose novel therapeutic strategies or improvements to existing therapies, such as novel drug targets, therapeutic modalities and agents, treatment combinations, and drug delivery systems.

  Treatments may address any stage in the continuum of care, including local therapies such as surgery or radiation, systemic therapies, as well as therapies targeting recurrent and refractory disease. Applications proposing new treatments or improvements to existing

[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.

therapies are highly encouraged to consider preserving patient quality of life in addition to improving survival outcomes.

- **Identify novel approaches for disease detection and monitoring**

  Applications should aim to identify novel approaches for screening, early-stage disease detection, accurate diagnosis, prognosis, and disease monitoring including therapeutic response and disease progression. Noninvasive or minimally invasive strategies are particularly encouraged and can include biomarkers, imaging approaches, genetic and epigenetic stratification/characterization, and radiomics.

- **Expand glioblastoma resources for the research and clinical communities**

  Applications should aim to develop or expand novel resources or tools such as biorepositories/biobanks with clinical annotation, databases for centralizing and sharing data, and/or clinical tools that will advance the field of glioblastoma research and ultimately improve outcomes for individuals with glioblastoma. Resources must be made available to the scientific and/or clinical community.

II.B. Award Information

Intent of the Transformative Consortium Award

The GBMRP recognizes the critical need for improved outcomes for individuals with glioblastoma. The GBMRP FY24 Transformative Consortium Award (TCA) is designed to support a multidisciplinary collaborative effort of at least four, but not more than five, distinct yet complementary projects that collectively address a central hypothesis. Applications for the TCA may propose clinical or translational research projects and/or clinical trials and must address at least one of the FY24 GBMRP Areas of Emphasis. This award requires a team-based approach by a consortium of exceptional researchers and at least one consumer advocate, whose collaborative efforts will catalyze scientific discovery, drive innovation, and make breakthroughs that could not be accomplished by a single investigator or group.

Key Aspects of the Transformative Consortium Award

Consortium Structure and Oversight

The FY24 GBMRP TCA is structured to accommodate four to five Principal Investigators (PIs) (the Consortium Director and at least three additional Project Team PIs but no more than four Project Team PIs). No more than two Project Teams, including the Consortium Director, may be based at one institution. ***The Consortium Director is responsible for the day-to-day management of the consortium, as well as for leading their own project team.*** The Consortium Director, together with the Project Team PIs, are jointly responsible for leading and executing the proposed research projects that are integrated into a cohesive strategy that will fundamentally and significantly transform the glioblastoma landscape.

Applications should include a robust consortium of researchers with the combined backgrounds and glioblastoma-related expertise to enable successful conduct of the proposed research.

Emphasis must be placed on integrating the most highly qualified investigators to focus on the research question(s), regardless of the investigators' locations. These investigators must include highly accomplished scientists and clinicians in the targeted areas of research who collectively represent the best team to solve the problem(s) identified. The proposed research effort should be broad enough to require a multidisciplinary approach that is reflected in the composition of the consortium team.

The Consortium Director and Project Team PIs each have different application submission requirements; however, all PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. If recommended for funding, each PI will be named on separate awards to the recipient organizations. For individual submission requirements of the Consortium Director and Project Team PIs, refer to Section II.D.2, Content and Form of the Application Submission.

Consortium Director: The Consortium Director will be responsible for the majority of the administrative tasks associated with application submission and the day-to-day management of the consortium. In addition, the Consortium Director will be responsible for leading their own project team. The Consortium Director is required to commit a minimum level of time and effort of 25% to direct and manage an initiative of this magnitude, as well as lead their own project team. The Consortium Director must have the scientific ability and proven administrative ability to oversee large research programs; and a proven record of leadership, including experience in the management of multifaceted and multidisciplinary projects. The Consortium Director should create an environment that facilitates the advancement of clinical and translational research efforts while also fostering and supporting innovation and creativity, with consistent, intensive interaction with the Project Teams in a way that engages all members of the consortium in all aspects of the research projects. A portion of the total direct budget costs must be reserved for a program manager to assist in the day-to-day management of consortium activities.

Consumer Advocate(s): Applications are required to integrate consumer advocate involvement into every aspect of the proposed consortium's activities. The consortium team must include at least one glioblastoma consumer advocate. As a lay representative, the consumer advocate(s) must be an individual who was diagnosed with glioblastoma, a family member of someone with glioblastoma, or a bereaved family member. The consumer advocate(s) should be part of a glioblastoma or brain tumor advocacy organization, and their role in the consortium should be independent of their affiliation. They cannot be employees of any of the institutions participating in the application. They must have a high level of familiarity and comfort with science and current issues in glioblastoma research.

The glioblastoma consumer advocate(s) must have an active role in every aspect of the proposed consortium's work ***including consortium conception and design***, decision-making and oversight, program evaluation, and dissemination of information to the public. Consumer advocate(s) must be integrated into and play an active role in the leadership and decision-making committees for the consortium.

Steering Committee: The consortium will establish a Steering Committee, to include the Consortium Director as Chair, Project Team PIs, at least one consumer advocate, and one expert in military health as members. Military health experts may be active-duty or retired Service Members with experience in military health and cancer, or U.S. Department of Veterans Affairs

(VA) representatives with a deep understanding of military health and cancer. Steering Committee advocates and military health experts may be existing team members at the Project Team sites or consulting team members. The application should clearly explain how the Steering Committee will monitor the status of ongoing consortium studies and review research progress.

Oversight: The Consortium Director, Project Team PIs, and consumer advocate(s) will be required to present an update on progress toward accomplishing research milestones and goals of the consortium and of each project at an annual In-Progress Review (IPR) Meeting for the TCA. The intent of the IPR meeting is to assess research progress, address problems, and define future directions. Annual IPR meetings will be held at the conclusion of year 1 and every subsequent year in the period of performance and will be attended by members of the GBMRP Programmatic Panel, CDMRP staff, and the USAMRAA Grants Officer to facilitate oversight and provide feedback to the consortium. IPR meetings will either be held in person in the National Capital Region or virtually, at the discretion of the government.

In addition to IPR meetings, the consortium must hold biannual workshops, which may be held at the PIs' institutions or virtually, to facilitate ongoing communication and exchange of information within the consortium, as well as with the steering committee.

Research Projects

Each Project Team, including the Consortium Director, must include a proposed project in the application; therefore, a minimum of four but up to five research projects must be proposed. Research projects should address distinct but complementary aspects of a central hypothesis and at least one of the FY24 GBMRP Areas of Emphasis. Research projects may include translational and clinical research involving human subjects and human anatomical substances, and/or clinical trials. Projects must demonstrate solid scientific rationale, and applications **must include published and/or preliminary data** that support the feasibility of their hypotheses and/or approaches.

While individual projects should be capable of standing on their own high scientific merits, they should also be interrelated under a central hypothesis and synergistic to advance a solution beyond what would be possible through individual efforts. Each project should propose a unique approach to addressing specific gaps in glioblastoma research and clinical care and be capable of producing research findings with potential to transform the glioblastoma landscape. This award mechanism is **not** intended to support a series of research projects that are dependent on the success of the other project(s).

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

Clinical trials are allowed.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102), "Definitions for Purposes of this Policy," as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a

placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects.[2] 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.

Other Important Considerations

Relevance to Military Health: The advancement of knowledge in glioblastoma research, patient care, and/or treatment options in the Military Health System is critical. Therefore, the GBMRP seeks to support research that is relevant to the health care needs of Service Members, Veterans, and/or their Families. PIs are strongly encouraged to consider the following examples of how a project may demonstrate relevance to military health:

- Use of military or Veteran populations, biospecimens, data/databases, or programs in the proposed research.
- Applications from investigators within the military services and applications involving multidisciplinary collaborations among academia, industry, the military services, VA, and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families.

[2] 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 45 CFR 46.104 of the Common Rule, "Exempt Research."

- Explanation of how the project addresses an aspect of glioblastoma that has relevance to or is unique to Service Members, Veterans, and/or their Families.

Rigor of Experimental Design: 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 Landis (2012).[3] 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.

CDMRP-Wide Encouragements

The following encouragements are broadly applicable across many of the CDMRP-managed programs, not just the GBMRP. Investigators are encouraged to consider addressing these areas in their applications if doing so is appropriate for their line of research and meets the intent of the FY24 GBMRP TCA.

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, the CDMRP encourages applicants to review the recommendations (https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research) and submit research ideas that address these recommendations provided they are within the limitations of this funding opportunity and 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: The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

Funding Details

The types of awards made under the program announcement will be cooperative agreements (31 USC 6305, "Using Cooperative Agreements") based on anticipated "substantial involvement" on the part of the CDMRP. Substantial involvement includes assistance, guidance, coordination, and/or participation in project activities, including but not limited to, IPR Meetings.

[3] Landis SC, et al. 2012. A call for transparent reporting to optimize the predictive value of preclinical research. *Nature* 490:187-191.

The anticipated total costs budgeted for the entire period of performance for an FY24 GBMRP TCA application, including the Consortium Director and Project Team PIs, should not exceed **$9.09M**. 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 $9.09M to fund approximately one Transformative Consortium Award application. The CDMRP GBMRP anticipates allocating approximately $4.38M of the FY24 GBMRP appropriation and approximately $4.71M of FY24 Defense Health Program (DHP) restoral congressional special interest funding for an anticipated total award cost of $9.09M.

The 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: Refers to 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.

II.C.1.b. Principal Investigator

- **Consortium Director**

  To be named as the Consortium Director (or Initiating PI) on the application, the PI must:

  - Be an independent investigator at or above the level of Associate Professor (or equivalent).

- Commit at least 25% level of effort to direct and manage the consortium **and** to lead their own project team.

An investigator may be named as Consortium Director on only one pre-application or full application submitted under this funding opportunity.

- **PIs for the Project Teams:**

To be named as a Project Team (or Partnering) PI on the application, the PI must:

- Be an independent investigator at any career level.
- Commit at least 10% level of effort to direct and manage a Project Team site.

There are no limits on the number of pre-applications or full applications for which an investigator may be named as a Project Team PI for this funding opportunity.

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.

For general information on required qualifications for applicants, refer to the General Application Instructions, Section II.A., Eligible Applicant Organizations.

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

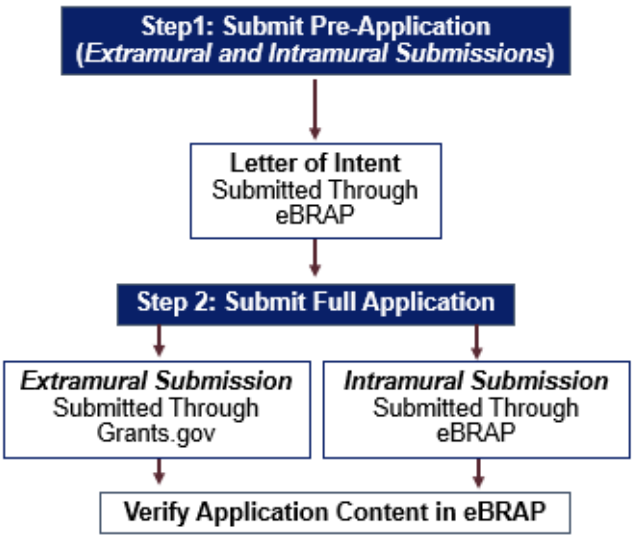
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural versus intramural), certain aspects of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

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

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

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

Application Submission Workflow



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524GBMRPTCA 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 HT942524GBMRPTCA 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 funding cycle is prohibited and will result in administrative withdrawal of the duplicative application(s).

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

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

FY24 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

Regardless of submission type (i.e., extramural or intramural), all pre-application components must be submitted by the Consortium Director through eBRAP (https://eBRAP.org/), including the submission of contact information for each Project Team PI.

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.

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:
No Clinical Trial	Transformative Consortium Award
Clinical Trial	Transformative Consortium Award – Clinical Trial

After the Consortium Director confirms submission of the pre-application, the Project Team PIs will be notified of the pre-application submission via an email from eBRAP. ***The Project Team***

PIs must follow the link in the notification email to associate the partnering pre-application with their eBRAP account. If not previously registered, the Project Team PIs must register in eBRAP.

After associating the pre-application with their eBRAP account, the Project Team PIs 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).

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

- The Project Team PIs will not be able to view and modify their full application during the verification period in eBRAP.
- Any intramural Project Team PI will not be able to submit their full application package components to eBRAP.

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 additional information on pre-application submission):

Note: Upload documents as individual PDF files unless otherwise noted.

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the FY24 GBMRP Area(s) of Emphasis to be addressed, consortium team, proposed research, and how the consortium intends to address a major problem in a way that could not be accomplished by a single investigator or group.

  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

The CDMRP requires separate full application package submissions for the Consortium Director and each Project Team 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 Consortium Director and Project Team PIs during pre-application submission. ***All associated applications (the Consortium Director's and each Project Team PI's) must be submitted by the full application submission deadline.***

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 CMDRP 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 Consortium Director

Each application submission must include the completed full application package for this program announcement. See Section II.H.3, Full Application Submission Checklist, 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 (20-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 consortium in detail using the outline below.

  - **Area(s) of Emphasis:** Identify which FY24 GBMRP Area(s) of Emphasis the proposed research will address and how the proposed research, if successful, will fill a gap in glioblastoma research and clinical care. Describe how the consortium's

fundamental goals and expected outcomes will fundamentally and significantly transform the glioblastoma landscape.

- **Consortium Structure:** Briefly describe the consortium's structure and organization to include the Consortium Director, Project Teams, Consumer Advocate(s), and Steering Committee. Describe how the consortium organizational structure and strategy establishes a collaborative, multidisciplinary effort that is integrated into a cohesive approach that will catalyze scientific discovery, drive innovation and make breakthroughs that could not be accomplished by a single investigator or group. A full description of the consortium team, management and execution, and communication will be provided in Attachment 7, Consortium Plan.

- **Research and Objectives:** Briefly explain the consortium's proposed projects that will each be led by the Consortium Director and Project Team PIs and explain the objective(s) to be reached by each project. Explain how the projects form a coherent plan to address a central hypothesis. Identify the key points of interaction among the projects and how such interaction will create synergy to address the FY24 GBMRP Area(s) of Emphasis more effectively than if the projects were conducted independently.

- **Project Teams and Proposed Projects:** Consortia should have at least four, but no more than five, project teams, each investigating distinct but complementary projects under the central hypothesis. One project team will be led by the Consortium Director and the remaining three or four project teams will be led by Project Team PIs. For each proposed project (either four or five total with one led by the Consortium Director), provide the following details using this outline. Start each project on a separate page; ***three-page limit*** for each project within the project narrative section:

  - **Title:** Provide a title for each project.

  - **Project Leader:** Identify the project leader (either the Consortium Director or one of the three to four Project Team PIs) and any key personnel, as appropriate.

  - **Background:** Describe the rationale for the project and reasoning on which the proposed research is based. Provide sufficient preliminary data to support the feasibility of the work proposed. The application must demonstrate logical reasoning and provide a sound scientific rationale as established through a critical review and analysis of published literature. For the proposed translational or clinical research project(s), and/or clinical trial(s), it is important to describe the studies showing proof of concept and, if applicable, efficacy in an in vivo system.

  - **Hypothesis/Objective:** State the hypothesis to be tested and/or the objective(s) to be reached.

  - **Specific Aims:** Concisely explain the project's specific aims to be funded by this award.

- **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for evaluation of their appropriateness and feasibility. Explain how this research strategy will meet the research goals. Address potential pitfalls and problem areas, and present alternative methods and approaches. If proposing translational research, provide a well-developed, well-integrated, and detailed research plan that supports the translational feasibility and promise of the approach. If the methodology is new or unusual, provide sufficient details for evaluation.

- **Clinical Research (no intervention; *if applicable*):** If human data sets, human anatomical substances (blood, tumor tissue, etc.), and/or human participants will be used, provide evidence supporting the availability of and access to the proposed specimens/populations required for the study. Include a detailed plan for the acquisition of samples or the recruitment of participants, and for acquiring any additional research resources necessary for conducting the proposed research project. For projects that propose using human data sets and/or specimens from biobank(s), biorepository(s), and/or ongoing or completed clinical trial(s), and if the manager or lead investigator is not the PI, one of the Project Leaders, or key personnel on the application, applicants should provide letter(s) of collaboration (see Attachment 2, Supporting Documentation) from the manager or lead investigator for the source. The letter should provide details about the applicant's access to the data sets/specimens and confirms the manager/lead investigator's commitment to provide the data sets/specimens. Describe the strategy for the inclusion of women and minorities in the study population or biological samples in Attachment 10, Inclusion of Women and Minorities.

- **Clinical Trials (includes an intervention; *if applicable*):** If human subjects or human biological samples will be used for a clinical trial(s), provide detailed plans for initiating and conducting the clinical trial(s) during the course of the award using Attachment 9, Clinical Trial Strategy Statement.

- **Statistical Plan:** Describe the statistical model and data analysis plan with respect to the study objectives. If applicable, specify the number of human subjects that will be enrolled. If multiple sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.

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

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

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

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

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

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

- **Letters of Collaboration:** 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.

- **Consumer Advocate Letter(s) of Commitment:** Provide letters signed by the glioblastoma consumer advocate(s) confirming their commitment to participate on the consortium team.

- **Commercial Entity Letters of Commitment *(if applicable)*:** If the proposed study involves the use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity indicating availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication to be tested.

- **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.

– **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Enclosure 3, Section 3.c of DoD Instruction 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.

– **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 nonprofit 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.

  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.

○ **Attachment 3: Technical Abstract (five-page limit for applications that propose four projects; six-page limit for applications that propose five projects): 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.

Clarity and completeness within the space limits are highly important.

Technical abstracts must be provided for the overall consortium (one-page), as well as each individual research project (one-page per project, up to five-pages), with each abstract starting on a new page.

The technical abstract for the **consortium** should be written using the outline below:

– **Background:** Present the ideas and reasoning behind the proposed research.

– **Area(s) of Emphasis:** State the FY24 GBMRP Area(s) of Emphasis that the proposed research will address. Describe how the expected outcomes will fundamentally and significantly transform the current glioblastoma landscape.

- **Consortium:** Specify the research team assembled by the consortium, including how the expertise and resources of each member will be combined to create a robust collaboration. Describe how the proposed consortium can catalyze scientific discovery, drive innovation, and make breakthroughs that could not be accomplished by a single investigator or group.

- **Projects and Objective:** Briefly explain the consortium's proposed projects that will be led by the Consortium Director and Project Team PIs, and explain the objective(s) to be reached by each project. Explain how the projects are synergistic under a central hypothesis.

- **Impact:** Explain how the consortium will make a transformative impact on the lives of individuals with glioblastoma.

The technical abstract for ***each individual research project*** should be written using the outline below:

- **Title:** Provide the title of the research project.

- **Background:** Present the scientific rationale behind the proposed research project.

- **Hypothesis/Objectives:** State the hypothesis to be tested or the objective to be reached. Describe how the study hypothesis/objectives fit within the consortium's overall approach.

- **Specific Aims:** State the specific aims of the study.

- **Study Design:** Describe the study design, including the model system(s) that will be used and appropriate controls.

- **Impact:** Summarize how the proposed research project will make an important contribution for the glioblastoma research and/or clinical communities.

The abstract may include a header identifying the name of the attachment (e.g., "Technical Abstract") to aid the review of the application, as long as the page limit is not exceeded.

- **Attachment 4: Lay Abstract (five-page limit for applications that propose four projects; six-page limit for applications that propose five projects): 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.

Lay abstracts must be provided for the overall consortium (one page), as well as each individual research project (one page per project, up to five pages), with each abstract starting on a new page.

The lay abstract for the **consortium** should be written using the outline below:

- State the FY24 GBMRP Area(s) of Emphasis that the proposed research will address.
- Summarize how the proposed consortium establishes a multidisciplinary collaborative team whose research efforts will significantly transform the current glioblastoma landscape.
- Describe how the glioblastoma consumer advocate(s) will be integrated into the consortium.
- Summarize the ultimate applicability and impact of the research for individuals affected by glioblastoma. Include how the proposed research, if successful, will benefit Service Members, Veterans, their Families, and the American public.

The lay abstract for ***each individual research project*** in the consortium should be written using the outline below:

- Provide the title of the individual research project.
- Summarize the scientific rationale, objective, and aims for the individual proposed research project.
- For the individual proposed research project, describe the applicability of the research to glioblastoma patients considering the following points:
  - What types of patients will the proposed research help and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - Describe the short- and long-term goals that are related to glioblastoma patient care, outcomes, or survivorship. What is a reasonable expectation for success for the individual research project?

- **Attachment 5: Statement of Work (18-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 FY24 GBMRP TCA mechanism, refer to either the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" or "Example: Assembling a Generic Statement of Work", whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit the SOW as a PDF file.

An individual SOW should be included for the overall consortium (three-page limit) and for each research project (three-page limit per project). Start each project SOW on a new page and ensure the title of the research project is listed. Individual documents must be combined and uploaded as a single PDF.

The SOW for the overall consortium should outline the key milestones and communication plans described in the Consortium Plan. Each research project SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks related to the major tasks and milestones within the period of performance. The SOWs should only describe the tasks that would be funded by this award.

The SOW should include a feasible plan and timeline to conduct the research.

- **Attachment 6: Impact Statement (two-page limit): Upload as "Impact.pdf".** ***Do not restate the research strategy as part of the Impact Statement.***

  Impact statements must encompass the overall consortium, as well as each individual research project. The Impact Statement should be written using language that will be readily understood by readers without a background in science or medicine.

  - Articulate how the proposed consortium's research will be transformative and significantly advance the GBMRP's mission of driving scientific discovery and advances in diagnosis, treatment and quality of life for patients with glioblastoma.

  - For each of the proposed research projects, explain how the anticipated outcome(s) will impact glioblastoma patient care in the short or long term.

- **Attachment 7: Consortium Plan (five-page limit): Upload as "ConsortiumPlan.pdf".**

  - **Consortium Team and Environment:**

    - Explain how the consortium brings different disciplines together to address improving glioblastoma outcomes with a cohesive and integrated approach that will catalyze scientific discovery, drive innovation and make breakthroughs that could not be accomplished by a single investigator or group.

    - Describe how the Consortium Director's research experience and leadership skills make them well qualified to be the Consortium Director. Include previous experience with collaborative team science and an ability to direct and oversee a multi-institutional research effort.

    - Describe how each Project Team PI will bring a different strength and/or expertise to the application. Describe how the combined expertise and resources of the Consortium Director and each Project Team PI in the consortium will create a robust, synergistic collaboration to better address the research question(s),

and explain why the work should be done together rather than through separate efforts.

- Explain how the consumer advocate(s) will be integrated into the consortium and represent the perspective of the patient population(s) most relevant to the consortium's proposed work.

- Describe the research environments and how each of the facilities and resources at all of the institutions will support the research requirements and the projects.

– **Consortium Management and Execution Plan:**

- Discuss the organization, oversight function, and operation of the Steering Committee and any additional committees or working groups that will monitor the status of ongoing consortium studies and review research progress. Include an organizational chart identifying the roles of all team members, including the consumer advocate(s).

- Describe how the consortium will be organized and managed to ensure integration across the consortium in all aspects, and how the proposed design will help meet the consortium goals.

- Present a management plan to facilitate Project Team interactions, adherence to regulatory requirements, administrative interactions, and oversight by the Steering Committee.

- Provide a plan for ensuring the standardization of procedures among staff and across sites.

- Specify the processes and tools to be used to achieve consortium management and research goals.

- Identify critical milestones and timelines, and present a plan for assessing individual project performance and progress.

- Describe procedures to maximize the use of resources and eliminate unnecessary duplication of efforts.

- The application should include a program manager who will guide the overall administrative management of the consortium.

– **Communication Plan:**

- Describe plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all PIs and organizations participating in the project. Address how data, specimens, and/or products obtained during the study will be handled.

- **Attachment 8: Consumer Advocate Statement (one-page limit): Upload as "ConsumerAdvocate.pdf".** The Consumer Advocate Statement should be written by the Consortium Director. Provide the name(s) of at least one consumer advocate and their affiliation with a glioblastoma or brain tumor advocacy organization(s). Explain how the consumer advocate(s) contributed to the consortium conception and design. Describe the integral roles they will play in the planning, design, implementation, evaluation of the research, ongoing discussion, decisions and oversight, program evaluation, and dissemination of information to the public. Describe how the consumer advocate(s)' knowledge of current glioblastoma issues will contribute to the consortium. Explain how the consumer advocate(s)' experience and expertise will be integrated into the research projects and management of the consortium.

- **Attachment 9: Clinical Trial Strategy Statement, *if applicable* (no page limit): Upload as "Clinical.pdf".** ***This attachment is only required for applications that propose using funds from this award to conduct a clinical trial. If a Clinical Trial Strategy Statement is included with any application that does NOT propose a clinical trial, then the Clinical Trial Strategy Statement will be removed prior to the application being reviewed.*** **Do not duplicate information from the Project Narrative in the Clinical Trial Strategy Statement.**

  For each clinical trial proposed:

  - Describe the clinical trial team, including details regarding how the team possesses the appropriate expertise for conducting the proposed trial.

  - Identify the intervention to be tested and describe the projected outcomes. Describe how the proposed intervention compares with currently available interventions and/or standards of care. Include a discussion of any current clinical use of the intervention under investigation and/or details of its study in clinical trials for other indications (as appropriate). Provide preclinical and/or clinical evidence to support the safety of the intervention.

  - Demonstrate the availability of the intervention. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for conduct of the clinical trial.

  - Describe the type of clinical trial to be performed (e.g., treatment, prevention, diagnostic), the phase of trial and/or class of device (as appropriate), and the study model (e.g., single group, parallel, crossover).

  - Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (the population from who the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team has access to the proposed study population at each site and describe the efforts that will be made to achieve accrual goals. Address any potential barriers to accrual and plans for addressing unanticipated delays,

including a mitigation plan for slow or low enrollment or poor retention. Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress.

- List the inclusion and exclusion criteria for the proposed clinical trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide justification for exclusions. See Attachment 10, Inclusion of Women and Minorities for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.

- Describe the process for obtaining informed consent and any screening procedures required to determine eligibility for study participation.

- Outline the proposed clinical trial methodology and study variables in sufficient detail to demonstrate a clear course of action and justification. Define each arm/study group of the proposed trial, if applicable, and describe how group assignment will occur. Provide a detailed description of the primary and any secondary or interim endpoints/outcome measures, explain why they were chosen, and describe how and when they will be measured. Outline what measures will be used to minimize bias, including blinding and randomization procedures. Describe any other measures to be taken to reduce bias. Include a description of controls, as appropriate. Outline the timing and procedures planned during the follow-up period. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human participant will experience.

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

- Provide detailed plans for initiating the clinical trial within the first year of the award period of performance and conducting the clinical trial during the course of the award.

- If the proposed consortium involves clinical trials at more than one institution, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions.

    - Provide a regulatory submission plan for the master protocol and master consent form by the lead institution.

    - If the research involves more than one institution, a single Institutional Review Board (IRB) is required for all institutions located in the United States.

- Describe how data will be reported and how it will be ensured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable.

- **Clinical Monitoring Plan:** Describe how the study will be conducted by and monitored for current ICH E6 (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) Good Clinical Practice (GCP) compliance by an independent clinical trial monitor (or clinical research associate). The monitoring plan should describe the types of monitoring visits to be conducted, the intervals (based on level of risk), how corrective actions will be reported to the Sponsor and PI, and how they will be corrected and prevented by the clinical trial site/PI.

- **Regulatory Documentation:** For the purposes of this funding opportunity, Regulatory Agency refers to the FDA or any relevant international regulatory agency unless otherwise noted.

  - **For products/interventions that DO NOT require regulation by a Regulatory Agency:** Provide evidence that the clinical trial does not require regulation by a Regulatory Agency. No further regulatory documentation is required.

  - **For products that DO require regulation by a Regulatory Agency:** If the product is not currently FDA-approved, -licensed, or -cleared, and requires an Investigational New Drug/Investigational Device Exemption (IND/IDE) or equivalent, provide detailed plans for an FDA IND/IDE application submission within 60 days of the award. The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed study.

  - If available, provide documentation that:

    - Indicates the date of Regulatory Agency submission, application number, and Sponsor for any existing FDA applications in place.

    - Supports the feasibility of acquiring an active IND or IDE (and/or international equivalent) for the product.

    - Shows the communication from the FDA indicating the IND or IDE application is active/safe to proceed. The first page of the statement may include a header identifying the name of the attachment (e.g., "Clinical Trial Strategy") to aid the review of the application.

  - Describe how quality control will be addressed. Describe how compliance with current Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and GCP guidelines will be established, monitored, and maintained, as applicable.

- **Attachment 10: Inclusion of Women and Minorities (six-page limit): Upload as "Inclusion.pdf".** ***(Attachment 10 is only applicable and required for applications that propose clinical research and/or clinical trials.)*** Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study/studies, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, which is a three-page fillable PDF form that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. 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.

- **Attachment 11: Data and Research Resources Sharing Plan (two-page limit): Upload as "Sharing.pdf".** Describe how data and resources generated during the performance of the proposed research projects will be shared with the research community. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed projects. Describe whether the proposed plan for resource sharing includes existing publicly available curated glioblastoma repositories/data platforms or other resources with relevant repository parameters and mechanisms for broad access to data and samples; and whether the plan describes organizational and technical capabilities sufficient to share project data in a timely manner. Include plans for making raw data, tissue samples, and other resources developed as a part of the proposed research projects available to the scientific community. Articulate the plans to ensure the data and/or research resource(s) is/are accessible after the period of performance expires. Provide a milestone plan for data/resource dissemination.

  If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data and/or research resources sharing plan. Refer to the CDMRP "Policy on Data & Resources 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.

- **Attachment 12: Post-Award Transition Plan (three-page limit): Upload as "Transition.pdf".** Provide information on potential methods and strategies to move the consortium's findings to the next phases of development and/or clinical use following the successful completion of the award. Articulate this information for the overall effort as well as the individual projects. Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. The research team is also encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product(s) into the next phase of development. Provide the components listed below, as appropriate:

- Outline the projects' anticipated research outcome(s), resource(s), and/or product(s) (e.g. findings, methodology, intervention, device, resource).

- Describe the next logical steps to be taken **by the research team** upon successful completion of the projects to advance the anticipated research outcome(s)/ product(s)/resource(s), to the next stage of development. Include a description of collaborations and other resources that are in place or would be established during the period of performance to execute the next logical steps (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources).

- Describe/discuss the methods and strategies necessary for the research outcome(s)/ resource(s)/product(s) to impact glioblastoma patient standard of care and outcomes, even if those are long-term goals; include a timeline with defined milestones. Include details of the funding strategy necessary to transition to the next level of investigation, development, and/or commercialization. This may include commercial sponsorship, venture capital, federal or nonfederal funding opportunities, etc. Discuss the opportunities available and potential barriers that would impact the progress of commercializing and/or translating the research outcome(s)/product(s) into clinical practice.

- If applicable, details of the development plan and FDA regulatory strategy that will support the planned product indication, to include considerations for compliance with current GMP, GLP, and GCP guidelines. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy.

- If applicable, discuss ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award including a plan for resolving intellectual and material property issues among participating organizations. If the intellectual property rights are not owned by the performer(s), describe the planned next steps necessary to make the product available to the glioblastoma community.

- **Attachment 13: 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 14: 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, 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".
  - Include biographical sketches for all team members, including consumer advocate(s).
- **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.

  The Consortium Director and Project Team PIs must each have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Consortium Director should not include budget information for Project Team PIs 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 14.

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

The application submission process for each Project Team 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 (18-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 13: Representations *(Extramural submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 14: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

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

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

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

- **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".
  - Include biographical sketches for all team members, including consumer advocate(s).
- **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 Consortium Director and Project Team PIs 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 the Project Team PIs should not include budget information for the Consortium Director, 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 and upload 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 14.

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 **4** years.

The application's (Consortium Director and all Project Teams) combined total costs budgeted for the entire period of performance should not exceed **$9.09M**.

If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

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

For this award mechanism, direct costs must be requested for:

- Travel costs for the PIs and consumer advocate(s) to present project information or disseminate project results at biannual consortium workshops during the period of performance in years 1, 2, 3, and 4. For planning purposes, it should be assumed that these meetings will be held at one of the PIs' institutions or virtually (if necessary). These travel costs are in addition to those allowed for annual scientific/technical meetings.

- Travel costs for Consortium Director, Project Team PIs, and consumer advocate(s) to attend annual IPR Meetings during the period of performance in years 1, 2, 3, and 4. For planning purposes, it should be assumed that in-person meetings will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

- A program manager to assist in the day-to-day management of consortium activities.

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

- Consortium-related meetings, teleconferences, and travel between/among participating institutions.

- Costs related to identifying and acquiring research resources.

- Computers and software required to participate in the consortium.

- Other costs associated with planning and developing the consortium collaborations, communications, and resources.

- Costs for two investigators per Project Team to travel to one scientific/technical meeting per year, in addition to the required meetings described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY24 GBMRP Transformative Consortium Award.

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:

Scored Criteria for the Overall Consortium

- **Area of Emphasis**

    - To what extent the consortium's goals will address at least one of the FY24 GBMRP Areas of Emphasis; and how the expected outcomes will fundamentally and significantly transform the glioblastoma landscape.

- **Consortium Plan**
    - To what extent the consortium organizational structure and strategy establishes a collaborative, multidisciplinary effort that is integrated into a cohesive approach to address a central hypothesis.
    - To what extent the consortium structure brings together different disciplines that will catalyze scientific discovery, drive innovation and make breakthroughs that could not be accomplished by a single investigator or group.
    - How well the Consortium Director's research experience, experience with collaborative team science, and leadership skills make them qualified to be the Consortium Director directing and overseeing a multi-institutional research effort.
    - To what extent the assembled expertise and resources will create a robust, synergistic collaboration and will advance toward a solution that would not be possible through individual efforts.
    - How well the consumer advocate(s) is integrated into the consortium and represents the perspective of the patient population.
    - How appropriate the proposed research environments and facilities are to support the research requirements and the projects.
    - Whether the Steering Committee structure and operation will provide appropriate oversight function to monitor the status of ongoing consortium studies and review research progress.
    - How well the management plan will facilitate Project Team interactions, adherence to regulatory requirements, administrative interactions, and oversight by the Steering Committee.
    - To what extent procedures are described to ensure standardization among staff and across sites.
    - To what extent the processes and tools to achieve consortium management and research goals are appropriate.
    - To what extent critical milestones and timelines are identified; and the plan for assessing individual project performance and progress is appropriate.
    - To what extent procedures are described to maximize the use of resources and eliminate unnecessary duplication of efforts.
    - How appropriate the level of effort is for the Consortium Director, who must commit a minimum level of time and effort of 25% to direct and manage the consortium, as well as to lead their own project team.

- Whether a program manager will guide the overall administrative management of the consortium.

- To what extent the plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all PIs and organizations participating in the project are described.

- **Impact**

  - To what degree the proposed consortium's research will be transformative and significantly advance the GBMRP's mission of driving scientific discovery and advances in diagnosis, treatment, and quality of life for patients with glioblastoma.

  - To what degree the proposed consortium's research will impact glioblastoma patient care in the short and long term.

- **Consumer Advocate Statement**

  - Whether the application provides the name and glioblastoma or brain cancer advocacy organization(s) of at least one consumer advocate.

  - To what extent the consumer advocate(s) contributed to the consortium conception and design.

  - To what extent the consumer advocate(s) will participate in the planning, design, implementation, evaluation of the research, ongoing discussion, decisions and oversight, program evaluation, and dissemination of information to the public.

  - How well the consumer advocate(s)' knowledge of current glioblastoma issues will contribute to the consortium, and how they will be integrated into the research projects and management of the consortium.

- **Data and Research Resources Sharing Plan**

  - How well the plan for distribution of data and resource(s) are described, feasible, and appropriate.

  - Whether the proposed plan for data/resource sharing includes existing publicly available curated glioblastoma repositories/data platforms or other resources as appropriate, with relevant repository parameters and mechanisms for broad access to data and samples.

  - To what degree raw data, tissue samples, and other resources developed as a part of the proposed research projects will be made available to the scientific community.

  - Whether the plan describes organizational and technical capabilities sufficient to share project data in a timely manner.

- How well the plan ensures the data and/or research resource(s) will be accessible after the period of performance expires and a milestone plan for dissemination is appropriate.

- **Post-Award Transition Plan**

  - How well the application describes potential methods and strategies to move the consortium's findings to the next phases of development and/or clinical use following the successful completion of the award.

  - Whether the application describes collaborations and other resources required to execute the next logical steps to advance the anticipated research outcome(s)/product(s)/ resource(s).

  - Whether the application describes a funding strategy that will be used to bring the outcomes to the next phase of development and/or delivery to market or incorporation into patient care.

  - How well the application describes the methods and strategies necessary for the research outcome/product to impact glioblastoma patient standard of care and outcomes.

  - To what degree the application describes a feasible timeline and defined milestones for bringing outcomes to the next phase of development or near-term clinical investigation.

  - How well the application describes the funding strategy necessary to transition to the next level of investigation, development, and/or commercialization.

  - If applicable, how well the development plan and FDA regulatory strategy will support the planned product indication, to include considerations for compliance with current GMP, GLP, and GCP guidelines.

  - If applicable, whether the application describes numbers and types of studies proposed to reach approval, licensure, or clearance; the types of FDA meetings that will be held/planned; and the submission filing strategy.

  - If applicable, how well the application addresses ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award, and a plan for resolving intellectual and material property issues among participating organizations.

Scored Criteria for Each Individual Research Project

- **Research Strategy and Feasibility**

  - To what extent the scientific rationale supports the project and its feasibility, as demonstrated by logical reasoning, a critical review and analysis of the literature, and, as appropriate for the proposed research project, sufficient preliminary data are provided. If a clinical trial is proposed, whether the provided preliminary data justify the conduct of the trial.

- To what extent the hypothesis or objective, experimental design, methodology, and analyses are well-developed and support successful completion of the specific aims within the period of performance of the award.

- To what degree the experimental design, methods, and analyses including appropriate controls are appropriate and feasible.

- For clinical research projects other than clinical trials:

  - To what extent the applicant demonstrates the availability of human data sets, human anatomical substances, and/or human subjects, including a detailed plan for the acquisition of samples/resources and/or recruitment of human participants necessary for conducting the proposed research.

  - Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.

- How well the application acknowledges potential pitfalls and problem areas, and addresses alternative methods and approaches.

- Statistical Plan:

  - To what degree an appropriate statistical plan is provided, including power analysis, with respect to the study objectives.

- **Clinical Trial Strategy** ***(only applicable if a clinical trial is proposed):***

  For each Clinical Trial proposed:

  - Whether the project team possesses the appropriate expertise for conducting the proposed trial.

  - How the proposed intervention compares with currently available interventions and/or standards of care.

  - Whether the preclinical and/or clinical evidence provided supports the safety of the intervention.

  - To what extent the application demonstrates availability of the intervention and indicates who holds the intellectual property rights to the intervention.

  - Whether the type of clinical trial (e.g., treatment, prevention, diagnostic); phase of trial and/or class of device (as appropriate); and the study model (e.g., single group, parallel, crossover) proposed is appropriate to meet the project's objectives.

  - Whether the application demonstrates access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.

- How well the application identifies potential barriers to accrual (e.g., slow or low enrollment, poor retention) and unexpected delays and presents adequate mitigation plans to resolve them.

- How well the inclusion and exclusion criteria are justified, meet the needs of the proposed trial and take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population.

- Whether the strategies for the inclusion of women and minorities are appropriate to the objectives of the clinical research study and/or proposed clinical trial, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of participants. Whether a completed Inclusion Enrollment Report, providing anticipated enrollment table(s) for the inclusion of women and minorities, is included with the application.

- How well the clinical trial is designed with appropriate study variables, controls, and endpoints/outcome measures; including why they were chosen, and how and when they will be measured.

- Whether the measures taken to minimize bias are appropriate.

- Whether the plans for initiating the clinical trial within the first year of the award are well described and feasible.

- To what extent the regulatory submission plan for the master protocol and master consent form by the lead institution is appropriate.

- Whether the multi-institutional structure governing the research protocol across all participating institutions is well described and appropriate.

- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

- Whether the described clinical monitoring plan is appropriate for the proposed study.

- To what extent the application includes appropriate plans and/or documentation in support of Regulatory Agency submissions and/or approvals

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

- **Budget**

    - Whether the **total** costs exceed the allowable limit as published in the program announcement.

    - Whether the budget is appropriate for the proposed research.

- **Environment**
    - To what extent the scientific environment is appropriate for the proposed research projects.
    - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
    - To what extent the quality and level of institutional support are appropriate for the proposed research projects.
- **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 award mechanism
    - Relevance to the FY24 GBMRP Areas of Emphasis
    - Program portfolio composition
    - Relative impact

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors, as described in Section II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess.

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

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, "Definitions," 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), 32 CFR 22.415, "Standards."

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-managed 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 the Consortium Director or Project Team PIs are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis.

An organizational transfer of an award supporting the Consortium Director or Project Team PIs is discouraged. The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed.

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, "DoD Grant and Agreement Regulations," and 2 CFR, Chapter XI, "Department of Defense," 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 IACUC, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

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

II.F.4. Reporting

Annual technical progress reports as well as a final technical progress report will be required. For applications proposing clinical trials, quarterly and Annual Technical Reports, as well as a final technical 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.

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

Inclusion Enrollment Reporting: ***(only required for clinical research studies and clinical trials)*:** Enrollment reporting on the basis of sex/gender, race, and/or ethnicity using the PHS Inclusion Enrollment Report will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to SAM about certain civil, criminal, and

administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@grants.gov

II.H. Other Information

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

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- 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 proposed research; 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: (1) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds; and/or (2) 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.

- The Consortium Director or Project Team PIs do not meet the eligibility criteria.
- Submission of the same research project to different funding opportunities within the same program and funding cycle.
- The main subject of the research is not glioblastoma IDH-wildtype.
- The application does not address at least one of the FY24 GBMRP Areas of Emphasis and adequate justification for exception was not provided.
- Application fails to name at least one glioblastoma consumer advocate as required by this program announcement.
- All associated (Consortium Director and each Project Team PI) applications are not submitted by the deadline.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded	
	Consortium Director	Project Team PIs
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐	☐
Attachments		
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐	
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐	
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐	
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐	
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐	
Consortium Plan – Attachment 7, upload as "ConsortiumPlan.pdf"	☐	
Consumer Advocate Statement – Attachment 8, upload as "ConsumerAdvocate.pdf"	☐	
Clinical Trial Strategy Statement – Attachment 9, upload as "Clinical.pdf" if applicable	☐	
Inclusion of Women and Minorities – Attachment 10, upload as "Inclusion.pdf" if applicable	☐	
Data and Research Resources Sharing Plan – Attachment 11, upload as "Sharing.pdf"	☐	
Post-Award Transition Plan – Attachment 12, upload as "Transition.pdf"	☐	
Representations *(Extramural submissions only)* – Attachment 13, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 14, upload as "IGBudget.pdf"	☐	☐
Research & Related Personal Data	☐	☐

Full Application Components	Uploaded	
	Consortium Director	**Project Team PIs**
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 (Support_LastName.pdf) for each senior/key person	☐	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification (BudgetJustification.pdf)	☐	☐
Research & Related Budget *(Intramural submissions only)* Include budget justification (BudgetJustification.pdf)	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ARRIVE	Animal Research: Reporting In Vivo Experiments Guidelines 2.0
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GBMRP	Glioblastoma Research Program
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IACUC	Institutional Animal Care and Use Committee
ICH E6	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDE	Investigational Device Exemption
IDH	Isocitrate Dehydrogenase
IND	Investigational New Drug
IPR	In-Progress Review
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TCA	Transformative Consortium Award
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