

The Brain Tumor Funders' Collaborative

American Brain Tumor Association * Brain Tumour Foundation of Canada
Children's Brain Tumor Foundation * Goldhirsh Foundation * Ben and Catherine Ivy Foundation
James S. McDonnell Foundation * National Brain Tumor Society * Sontag Foundation

Call for Grant Proposals

New Approaches for Developing Tools for Non-Invasive or Minimally-Invasive Monitoring of Pediatric and Adult Gliomas

Proposals Deadline: June 15, 2009 5PM CDT

Background

Over the past year, the Brain Tumor Funders' Collaborative (BTFC) convened a series of workshops evaluating the brain tumor research landscape with the aim of identifying research questions that present challenges to the efficient design and development of new therapeutic interventions. BTFC seeks to fund research that overcomes such obstacles and contributes towards progress against adult and pediatric glioma. These conversations have resulted in BTFC's decision to invest in the development of new tools and approaches that would lead to the non-invasive (or minimally-invasive) determination of tumor responsiveness to experimental interventions in clinical trials and the treatment of brain tumors in patients.

The BTFC intent is to **accelerate** translational and clinical research of direct relevance to the care of patients with brain tumors. As such, projects funded as a result of this call for proposals must involve human subjects directly or must be focused on studies of tissues or fluids obtained from human subjects. Funded projects must show a direct connection between the proposed research plan and the utilization of the anticipated research results in the conduct of human clinical trials and in the clinical delivery of therapies.

The BTFC initiative is based on the need to **rapidly** and dynamically determine how and when tumors are responding to experimental therapeutics or established therapies. Response markers that inform a positive response (for example that the treatment is achieving the desired result) or negative response (for example that the tumor is not impacted or is becoming therapeutically resistant) in *individual patients* could enhance the design of clinical trials and guide the management of patient care.

To facilitate the design, development, feasibility testing, and validation of non- (or minimally-) invasive response markers the BTFC will support up to ten 1 year grants with budgets up to, but not exceeding \$100,000 direct costs. BTFC policies do not permit indirect cost recoveries. Following review of each funded project's progress, the BTFC could provide additional support as warranted to the projects demonstrating the greatest likelihood of continued success and accomplishment of the overarching goal of bringing new tools into widespread use.

The BTFC anticipates that proposals submitted in response to this call for proposals may comprise a broad span across the research spectrum. We are willing to consider promising but as of yet completely novel and

untested approaches as well as proposals requesting funding for more developed approaches requiring final feasibility testing, or validation in brain tumor patients, or demonstrations of generalizability across sites.

BTFC's goal is to accelerate the utilization of glial tumor response markers as a component of the overall effort to quickly determine the clinical potential of treatments. We anticipate that the availability of validated response markers will enhance the efficiency and effectiveness of both research and clinical care.

- The focus of the new funding initiative is on *both* pediatric and adult gliomas.
- Translating knowledge acquired from basic science into effective clinical applications requires the ability to monitor dynamic tumor responses in clinical trials to new interventions.
- The short survival times of many brain tumor patients requires that the effectiveness of any treatment be determined quickly. Tools are needed that can facilitate on-line decision-making.
- The projects need not focus exclusively on tumor cell biology or physiology. Developing effective tools and techniques for monitoring tumor responsiveness may arise from entirely new ways of detecting tumor response characteristics.
- Although individual investigators or laboratories can respond to this call for proposals, the BTFC recognizes that translating preclinical results into clinical applications often requires collaborative teams integrated across the disciplines of laboratory science and clinical medicine. The investigators making up a collaborative team may be drawn from different disciplines and different institutions, and from nonprofit and for-profit organizations.
- BTFC funds can be used by collaborative teams for ongoing communication and planning efforts as part of a comprehensive research design. We recognize, through our own experiences, that building effective collaboration requires hard work, time, administrative support, and a strong desire to work together.

Brain Tumor Response Marker Initiative: Who is Eligible?

- Proposals can be initiated by either researchers or clinicians.
- Proposals focusing on developing mechanisms appropriate to both adult and pediatric glial tumors are strongly encouraged though it is recognized that specific response markers may differ from tumor type to tumor type.
- If a proposal is team-based, the teams should include clinical expertise as well as expertise in brain tumor research and potentially expertise from other fields such as, but not limited to, genomics, biophysics, and mathematics/bioinformatics.
- Proposals submitted on behalf of a collaborative must have one individual identified as the project manager. Grant contracts will be negotiated with a single US-based 501(c)(3), or equivalent Canadian institution identified as the sponsoring institution accepting responsibility for the scientific, administrative, and financial management of the overall project including all subcontracts.

- Collaborative components, other than the sponsoring institution accepting the grant, need not be not-for-profit institutions. Collaborative components may be located outside the U.S. or Canada.

Scope of Grants

- Laboratories or collaborative networks proposing approaches for monitoring a patient's tumor response characteristics can request funding for 1 year's duration for up to \$100,000 in direct costs only. Funds can be used as needed to carry out the planned project. The BTFC anticipates budgets will request typical research expenditures. Funds can be used for planning, feasibility testing, and/or validation across sites, workshops, or other activities required to conceptually and practically advance the development of useful tools and techniques responsive to the BTFC goals articulated in this RFA.
- Established tools and techniques may be used for the identification of response markers (or sets of markers) whose non- (minimally-) invasive detection would provide valid tumor responses.
- Under the guidelines of this RFA, BTFC support is not intended for the development of diagnostic tests for detection of brain tumors nor is it intended to support approaches where the primary aim is demonstrating that a drug reaches its intended target without revealing whether the agent is achieving its intended tumor response. The BTFC is interested in supporting research identifying markers reflective of the biologic/physiologic responses of tumors to treatments and reflective of a patient's response to therapy.
- The research goals must include time-lines and benchmarks measurable in real-world outcomes; all goals must be clearly articulated and measurable within the project timeline. Outcomes measures must be directly relevant to the development of patient therapies and achieving improved clinical outcomes.
- Team proposals must detail the collaborative aspects of the project by specifically addressing how the teams will solve intellectual property issues as well as issues such as, but not limited to, data-sharing and joint publication.
- Each collaborative investigator must submit a brief letter (one page) stating a commitment to participate in the proposed activities.
- Each funded project must commit to sending representative(s) to an annual workshop if convened by the BTFC. The expenses for such meetings will be born by the BTFC and should not be budgeted for in the proposal. BTFC meetings can include representatives from the funding organizations, expert scientific consultants, and other invited participants.

Submission of proposals

Proposals must be submitted in the form of a **2500 word (maximum) narrative**. The BTFC decision to request brief proposals is deliberate; applicants should make every effort to keep the language of the proposals crisp, to the point, and free of unnecessary jargon. Lengthy introductions summarizing information well-known to individuals familiar with brain tumors should be avoided. Preliminary data should be provided as needed to

support the proposed research. Proposals should not contain appendices or other attachments. Figures and tables should be used judiciously, and the accompanying legends should be brief. Figure legends will not be included as part of the allowed word count but use of figure legends to circumvent the allowed word count could lead the BTFC to disqualify a proposal. Proposals must be submitted electronically via the BTFC website as a single PDF file. The PDF file must contain all required information. Proposals will be reviewed against the criteria outlined above. Proposals not conforming to the guidelines will be rejected without review.

Proposals should contain the following items assembled into a single PDF in the order listed:

1. BTFC cover sheet ([available here](#))
2. Proposal narrative
3. A budget plan explaining why the funds are needed and how the funds will be expended.
4. NIH biosketch ([file available at this link](#)) for the individual serving as project manager.
5. Brief narrative biography (including website address if available) for all project personnel. The narrative should provide details of an individual's expertise and the role he or she will take in the proposed research plan.
6. Project time line

Review Process

Proposals will be scientifically reviewed by a panel of experts in consultation with the members of the Brain Tumor Funders' Collaborative.

Timeline

June 15, 2009	Proposals must be uploaded to the BTFC website by 5:00 P.M. CDT
Fall 2009	BTFC announces awards
Fall 2010	Anticipated review of funded pilot project progress
Winter 2010	As warranted by review, BTFC negotiates continued funding of selected projects.