Operations, Biostatistics and Data Management Core
St. Jude Children's Research Hospital
262 Danny Thomas Place, Memphis, TN 38105-2794
Telephone: 901-595-2715
Fax 901-595-4585
pbtc.org

New Member Institution Application

Institution:

Principal Investigator:

General Considerations (max 500 words)

Provide an overall assessment of your institution including an overview of why your institution should be considered for membership in the PBTC. Include your institution's organizational structure to indicate who in your institution approves the commitment to the PBTC (i.e., Division Chief, Department Chair, Cancer Center Director, Dean, etc.) and provide letters of support as appropriate and relevant.

Clinical and Investigational Competency (max 500 words)

Document the clinical and research competence (clinical trial, basic and translational research) among your institution's brain tumor team including pediatric neuro-oncologists, neurosurgeons, radiation oncologists, neuroradiologists, neuropathologists, biologists, and other key members of your patient care/clinical research team relevant to development of and participation in clinical trials.

Neuroimaging Expertise and Equipment (max 500 words)

Describe your institution's neuroimaging faculty and clinical and research expertise and resources. Please include your current or imminent neuroimaging equipment (e.g., MRI- list units with tesla strength, software version, types of contrast used), PET facilities with equipment and available radiotracers, imaging equipment and brain imaging research at site, advanced imaging capabilities (e.g., single or multivoxel MR spectroscopy, DWI, DTI, MR perfusion, ASL perfusion, molecular imaging and functional MR) and whether or not your institution has intraoperative MRI capability. Your institution must also have the capability and resources to process, anonymize, transfer and upload image files for central review and other study related objectives.

Patient Accrual (max 500 words)

PBTC institutions are expected to enroll 10-12 patients per year on phase I/II PBTC studies. Provide the number of CNS tumor patients ≤21 years of age first seen at your institution during the past 3 calendar or academic years and specifically provide numbers for the subsets with newly diagnosed and recurrent DIPG, newly diagnosed and recurrent high-grade glioma, recurrent medulloblastoma, newly diagnosed and recurrent low-grade glioma, newly diagnosed and recurrent ependymoma, and newly diagnosed infants/children under 3 years old with embryonal or other high grade tumors. Also specify the number of patients with recurrent disease treated on clinical trials at your institution during each of the last 3 calendar or academic years. If relevant, include number of older subjects with "pediatric tumors" such as adult medulloblastoma seen at your institution as separate categories.

Experience with CNS Phase I and II Trials (max 500 words)

Describe your institution's experience with CNS phase I and Phase II trials. Provide the titles of each CNS pediatric phase I and II study open to accrual at your institution in the past 3 years and the number of institutional patients enrolled in each; this may include institutional or multi-institutional trials. Describe any cooperative group experience and study chair experience with either institutional, industry sponsored or cooperative group phase I and II trials (CNS and non-CNS).

Clinical and Laboratory Expertise (max 500 words)

PBTC institutions must have clinical and laboratory expertise interested in the Consortium's activities and relevant to potential protocol development or management of correlative study components in biology, immunology, neuropathology, PK, etc. Provide evidence of development and completion of clinical and correlative projects (in brain tumor biology and/or neuroimaging).

Academic Commitment and Scientific Contributions to the Consortium (max 500 words)

Describe how investigators from your institution will further the goals and research mission of the PBTC, including investigators from clinical neuro-oncology disciplines and those in translational research (neuropathology, molecular and tumor biology, and advanced neuroimaging).Detail any unique capabilities or expertise your institution may bring to the Consortium.

Competing Institutional Commitments (max 500 words)

PBTC Member institutions are expected to prioritize PBTC trials above all others. Assert that if chosen, your institution will abide by this requirement. Describe any current or projected commitments within your institution or in your participation in multi-institutional activities outside of COG that might limit your participation in PBTC studies.

Data Management (max 500 words)

PBTC institutions must have capabilities for data collection, management, and electronic submission (including redacted source documents and MRIs where HIPAA identifiers are replaced with PBTC identifiers). Describe your institution's data management capabilities and provide assurance that your institution will designate adequate CRA and other related resources to ensure timely data entry and query resolution. Furthermore, provide assurance that your institution 's information technology department will collaborate with the PBTC's computing staff on connectivity, firewall, security, and other computing issues.

Processing of Protocol-Required Specimens (max 500 words)

PBTC institutions must be able and willing to collect and ship appropriate pharmacologic and biologic specimens for patients entered on PBTC studies. Describe your institution's experience with the collection of these specimens in the CNS and non-CNS tumor settings and explain any concerns for participating in pharmacology and/or biology studies.

Established Clinical Trial and Research Administration Infrastructure (max 500 words)

Provide assurance that your institution possesses the clinical trial infrastructure (e.g. regulatory, clinical trials administration, legal/contracting, research nurse and CRA support, etc.) needed to support data intensive Phase I and II trials and is committed to allocate these resources for PBTC related activities. Special Note for Canadian Applicants: Canadian applicants must provide a detailed regulatory plan for agents under INDs and for efficient processes for executing study-specific agreements. (additional 500 words max)

Human Subject Protection (max 500 words)

Describe procedures in place for protection of human subjects and inclusion of minorities and females on trials. The PBTC has utilized NCI's Pediatric Central IRB as the IRB of record for all its clinical trials that were activated since 2017. Thus, all US-based full member institutions of the PBTC are required to have Institutional Authorization Agreements with Pediatric Central IRB. Special Note for Canadian Applicants: Canadian applicants must provide a detailed plan for protection of human subjects since they will have to operate outside NCI's Pediatric Central IRB structure. (additional 500 words max)