



PEDIATRIC BRAIN TUMOR CONSORTIUM (PBTC)

CONCEPT SUBMISSION AND REVIEW PROCEDURES

The procedure for PBTC Scientific Committee solicitation and review of protocol concept proposals has been established to encourage thorough reviews and discussions prior to the Scientific Committee voting (scoring) on whether a concept should be developed into a PBTC protocol. Two primary PBTC reviewers are assigned to provide thoughtful, detailed reviews of the concept. Two reviewers who are not members of the PBTC may be asked to review the concept. PBTC Scientific Committee members are asked to provide comments without scores during the initial review of the concept. These comments are sent to the submitting investigator for a response and posted on the web site, as they become available. The investigator has 10 days to respond to questions and comments. All comments and responses will be distributed to the PBTC Scientific Committee and the members will then provide an overall priority score. Concepts with a median priority score of 2.0 or less will be discussed at the monthly Steering Committee conference call concerning feasibility, costs of the study, and prioritization with consideration for the other LOIs and protocols under development at the Operations and Biostatistics Center (OBC) at that time.

CONCEPT SUBMISSIONS

Who May Submit

Any PBTC investigator may submit a concept for review. Non-PBTC investigators may also submit directly to the OBC and may serve in the capacity of protocol study chair (PSC) if the concept becomes a protocol. In the case of a non-PBTC investigator initiated protocol, the PCS's Institution will be recognized as a "PBTC Temporary Institution" for the duration of the protocol and may enroll patients only on that protocol.

Where to Submit

Concepts, in the format specified on the PBTC Web site, may be submitted via email to the OBC for distribution to the Scientific Committee. The PBTC concept submission form and email address are available on the PBTC Web site. The PBTC form may be substituted by another document as long as all elements in the PBTC form are addressed.

Timing of Submissions

Concepts may be submitted to the OBC at any time. All concepts to be discussed during the semi-annual meetings must be received by the OBC two weeks prior to the meeting. Concepts to be included in the semi-annual meeting book report must be received by the OBC six weeks prior to the meeting. It is not necessary to discuss a concept during a semi-annual meeting in order to have it reviewed and prioritized.

DISTRIBUTION OF CONCEPTS TO SCIENTIFIC COMMITTEE

(see Distribution of Concepts Flowchart)

Selecting External Reviewers

The Chair of the Steering Committee may provide the names of two non-PBTC investigators to review the concept. The submitting investigator may also suggest external reviewers. A request to review is sent to the potential reviewers. The identity of the outside reviewers is open to all and the reviewers are informed that their comments are not anonymous.

Selecting Primary Reviewers

Two primary reviewers are identified from within the PBTC by the Chair of the Steering Committee. The primary reviewers may be PBTC Scientific Committee members or PBTC institutional members with known relevant interest and expertise.

Distribution of Concepts for Comments

The OBC simultaneously sends the concept to the external reviewers, primary reviewers and PBTC Scientific Committee members. The concept review criteria form is included in the mailing. Comments are due within 2 weeks of distribution. Distribution is not held up if there are delays in obtaining willing external reviewers.

Concepts are reviewed in five areas: Scientific Rational, Novelty/Innovation, Study Design, Feasibility, and Patient and Family Considerations. The reviewers are requested to provide comment on these areas during this initial review. Scoring will take place after the investigator has an opportunity to respond to the review.

Circulating Reviewers Comments

Comments are sent to the submitting investigator and posted on the web site as they become available. A complete set of comments is sent to the PBTC Scientific Committee at the end of the 2 week review period. The submitting investigator has 10 days to respond to the reviewers' comments. The investigator's response is then circulated to the PBTC Scientific Committee for a final review and scoring.

Scoring

Scores are due within 1 week of distribution of the investigator's response. Concepts are given an Overall Priority Score using a modified NIH/NCI Continuous rating scale where:

- 1.0 – 1.5 = Outstanding
- 1.5 – 2.0 = Excellent
- 2.0– 2.5 = Very Good
- 2.5 – 3.0 = Good
- 3.0 – 4.0 = Acceptable
- 4.0 – 5.0 = Not Acceptable

All members of the PBTC Scientific Committee review and score all concepts unless the member submitted the concept, the member is at the same institution as the submitting investigator, or the member declares a conflict of interest for other reasons.

PRIORITIZATION OF CONCEPTS

Prioritization Scheme

Concepts are prioritized for development based on the scheme below.

Median Overall Scientific Committee Score	Development Category	Prioritization
1.0 – 2.0	A	Approved for LOI development. Feasibility, study costs and prioritization discussed at the PBTC Steering Committee conference call. If submitted and approved by CTEP, will be developed into PBTC protocols.
2.1 – 3.5	B	Revise and resubmit to Scientific Committee. Resubmission of the revised concept can occur twice. Resubmissions will be designated by suffixes of A and B, respectively.
3.6 – 5.0	C	NRF – no further reason for consideration. However one modified resubmission will be entertained. The resubmission will be designated with a suffix of A

Concepts receiving a median score of 2.0 or less will be discussed at the monthly Steering Committee conference call. Details such as costs of the study and feasibility will be discussed. Timelines for development of the concept into a Letter of Intent will be estimated based on the current LOI and protocol development occurring in the OBC at that time.

POSTING RESULTS

The submitting investigator is sent a concept disposition letter including the median final score received. The submitting investigator will become the Protocol Study Chair for Group A concepts. The concept and disposition will be posted on the PBTC member's only web site. After discussion and prioritization of the concept at the PBTC Steering Committee conference call, the submitting investigator will receive email correspondence from the OBC with a draft of the Letter of Intent or timelines for development of the concept into a Letter of Intent.

SUBMISSION OF LETTER OF INTENT

Concepts that have been prioritized for LOI development will be put into CTEP format by a Protocol Coordinator from the OBC. A Study Group will be formed to review the LOI prior to its submission to CTEP by the OBC. The submitting investigator and Steering Committee Chair work together to recommend study group members. If approved by CTEP, the LOI will be developed into a protocol.

The OBC maintains a database of concept dates of submission, scoring, and final disposition as well as the actual scores and comments.

Distribution of Concepts Flowchart

Investigator submits concept

PBTC Scientific Committee chair assigns 2 primary PBTC reviewers and provides names of potential external reviewers.

Concept distributed to the Scientific Committee for comment.

Concept distributed to external reviewers for comment

14 days

OBC compiles comments. Sends comments to investigator and posts on web site as comments accumulate.

Investigator responds to comments

10 days

Investigator's response distributed to Scientific Committee

7 days

Scientific Committee members provide final score for concept prioritization.

Discussed and prioritized at the next monthly Steering Committee conference call