

**Collaborative Network for Neuro-oncology Clinical Trials (CONNECT)**

**Letter of Intent (LOI) for Clinical Trial Proposal**

I. ADMINISTRATIVE

Title of Concept:

Concept Version Date: Study Chair Name (printed):

Study Chair Address: Study Chair Phone:

Study Chair e-mail:

Name(s) of co-chairs, if any:

II. DISEASE AND INTEGRAL MARKER SPECIFIC SECTION

Specify the Name of all the Study Diseases below

1. If study involves multiple diseases, please provide Disease Name and Disease Code for each disease.

2. Does the study involve any investigational (non-standard of care) integral marker(s) (e.g., laboratory test, imaging test) defined as test(s) that must be performed in order for the trial to proceed or for the trial data to be analyzed with respect to the primary endpoint?

Yes ☐ No ☐ Not Known ☐

III. ACCRUAL SECTION

Accrual Rate: \_\_\_\_\_ pts/month.

Total Expected Accrual: Minimum \_\_\_\_\_\_ Maximum \_\_\_\_\_\_

Projected Accrual Dates: Start \_\_\_\_\_ End: \_\_\_\_\_

Justification for accrual rate:

IV. SCIENCE SECTION

To enter text, click on the blank line under each question and type or paste text.

1. Specific hypotheses:

2. Objective(s) (it is preferable to specify one primary objective and secondary objectives):

2.1 Primary objective:

2.2 Major Secondary objective(s):

3. Background Information. This section should include a BRIEF description of the following:

3.1 Rationale for selected approach and trial design.

3.2 Discuss why this trial is important (include summary of clinical issues and competing study questions relevant to the trial setting) and potential impact on, for example, overall survival, quality of life or advances in proof of biologic principles. Also, how would research strategy or future clinical practice be altered by either positive or negative results?

3.3 All pertinent data (include phase 1-3 trial results, and any pilot or confidential data from companies that justify the use of the control and experimental arms).

4. Eligibility (include rationales for selecting or excluding particular cohorts):

5. Arms/Regimens:

5.1 Schema

5.2 Arms/Regimens

6. Statistical design:

6.1 Endpoint(s).

6.1.1 Primary Endpoint

6.1.2 Secondary Endpoint (if any)

6.2 Include any stratification to be used in the randomization.

6.3 Provide sample size with power justification.

6.4 Provide analysis plan including plans for formal interim analysis.

7. Feasibility (Discuss, as appropriate, size of eligible population, anticipated acceptance of trial by patients and referring physicians and experience with accrual to similar trials). Investigators must include:

7.1 Competing trials in CONNECT.

7.2 Competing trials in other U.S. or international Groups.

7.3 Competing company studies of which you are aware.

V. POTENTIAL EMBEDDED CORRELATIVE STUDY SECTION

Please provide below a BRIEF description (no more than a brief paragraph of 5 to 6 sentences) to indicate any primary integrated laboratory, imaging, or quality of life (QOL) embedded sub-study that the study team is planning should this concept be approved.

LABORATORY CORRELATIVE SCIENCE STUDY

Yes ☐ No ☐

Brief Description:

IMAGING CORRELATIVE SCIENCE STUDY

Yes ☐ No ☐

Brief Description:

QOL CORRELATIVE SCIENCE STUDY

Yes ☐ No ☐

Brief Description:

\***Please send completed form to Connect@cchmc.org**