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|  | **PHASE 2, 2/3 and 3 TRIAL  CONCEPT SUBMISSION, Version 4** | CLINICAL INVESTIGATIONS BRANCH |
| **National Cancer Institute**  **Division of Cancer Treatment and Diagnosis**  **Cancer Therapy Evaluation Program** | |

*NOTES: Concepts must be submitted in electronic format (tables or schema may be converted to .pdf format to assure accurate transfer). To complete the form electronically, use the mouse pointer or the Tab key to navigate. Select and enter text for each text field (the Insert key must be set to Off) or follow instruction when given. Submit by e-mail to PIO@CTEP.NCI.NIH.GOV. Each of the scientific sections should be sufficient to constitute the corresponding sections of a final protocol, but they should not be excessive or encyclopedic. Within these principles as a guide, there are no specific requirements or limitations on length.*

# I. ADMINISTRATIVE

|  |  |  |  |
| --- | --- | --- | --- |
| Title of Concept: |  | | |
| Sponsoring Organization’s Local Protocol Number: |  | | |
|  | | | |
| Study Chair Name (printed): |  | | |
| Study Chair Signature (optional): |  | Date: |  |
| Study Chair Address: |  | | |
|  |  | | |
|  |  | | |
| Study Chair Phone: |  | | |
| Study Chair Fax: |  | | |
| Study Chair e-mail: |  | | |
| Name(s) of co-chairs or discipline chairs, if any: |  | | |
| Group Chair/Cooperative Agreement Name: [Click here to enter name] | | | |  | | | |
| Group Chair Signature (optional): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |  | Date: |  |
| Group Chair Address: |  | | |
|  |  | | |
| Group Chair Phone: |  | | |
| Group Chair Fax: |  | | |
| Group Chair e-mail: |  | | |
| **NIH Grant Number**: |  | | |
| Study Statistician Name: |  | | |
| Study Statistician E-mail: |  | | |

If this trial is NOT proposed for activation in the Cancer Trials Support Unit (CTSU), please provide justification.

If this trial is NOT proposed for activation ASAP, planned date for activation and reason for delay:

# II. Phase of Study

Specify what type of phase this study will be conducted under (2 or 3).

**2 3 2/3**

# III. DISEASE SPECIFIC SECTION

Specify the Name and Code of the Study Diseases (MeDRA Code Disease list available on CTEP Web site, <http://ctep.cancer.gov/protocolDevelopment/codes_values.htm>.

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1.

2.

3.

If this disease is under a Steering Committee, please indicate if this Concept version has already been reviewed by the Task Force? **Yes No Not Known**

# IV. PHARMACEUTICAL SECTION

1. Specify the agent(s) to be used in the study:\*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Agent Name | Request for CTEP/PMB-distribution? | Is the agent Investiga-tional? | Who is the IND Holder? | NSC  Number[[1]](#footnote-1) | Placebo  Controlled? |
|  | Yes No | Yes No | Company Consortium CTEP  Group Investigator Other (Specify): |  | Yes No |
|  | Yes No | Yes No | Company Consortium CTEP  Group Investigator Other (Specify): |  | Yes No |
|  | Yes No | Yes No | Company Consortium CTEP  Group Investigator Other (Specify): |  | Yes No |
|  | Yes No | Yes No | Company Consortium CTEP  Group Investigator Other (Specify): |  | Yes No |
|  | Yes No | Yes No | Company Consortium CTEP  Group Investigator Other (Specify): |  | Yes No |
|  | Yes No | Yes No | Company Consortium CTEP  Group Investigator Other (Specify): |  | Yes No |

*\*For treatment protocols, include only anti-cancer agents.*

1. If CTEP is being requested to distribute any agents not under a CTEP IND, provide the reason for the request for each agent.

# V. ACCRUAL SECTION

Provide the following accrual information:

**Accrual Rate**: pts/month.

**Total Expected Accrual**: **Minimum** [Click here and enter] **Maximum** [Click here and enter]

**Projected Accrual Dates**: **Start** [Enter Month] / [Enter Year] **End**: [Enter Month] / [Enter Year]

(Please provide the justification for this accrual rate estimate. If the accrual estimate is based upon participation of other Groups, please have them submit letters of endorsement to the CTSU at the time of concept submission.)

# VI. 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 any number of secondary objectives):

2.1 Primary objective:

2.2 Secondary objective(s):

1. Background Information. This section should include 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 relevant 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).

(For publications cited, include either the NLM/Medline ID number or the URL address to permit retrieval of the full text or abstract by reviewers)

1. Eligibility (include rationales for selecting or excluding particular cohorts):
2. Arms/Regimens(include schema):
   1. Schema

5.2 Arms/Regimens

1. Statistical design in detail:

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 phase 3 trials in your Group.

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

7.3 Competing company studies of which you are aware.

# VII. EMBEDDED CORRELATIVE STUDY SECTION (if applicable) – Example: companion laboratory or imaging studies, or quality of life studies

*To enter text, click on the blank line under each question and type or paste text. If additional space is required, please include as an attachment.*

***PLEASE PROVIDE AN ANSWER TO THIS QUESTION* :**

Does the concept include any health-related quality of life (HRQoL) endpoints or other patient-reported outcomes (PROs)? \_\_\_Yes \_\_\_ No

1. Correlative study title:

1.1 Correlative study design (to include methods for obtaining samples, administering forms, or performing radiologic studies):

1.2 Specific hypotheses (include relevant background studies):

1.3 Statistical design (for each correlative study – include endpoints, sample size and monthly accrual rate):

2. Correlative study title:

2.1 Correlative study design (to include methods for obtaining samples, administering forms, or performing radiologic studies):

2.2 Specific hypotheses (include relevant background studies):

2.3 Statistical design (for each correlative study – include endpoints, sample size and monthly accrual rate):

3. Correlative study title:

3.1 Correlative study design (to include methods for obtaining samples, administering forms, or performing radiologic studies):

3.2 Specific hypotheses (include relevant background studies):

3.3 Statistical design (for each correlative study – include endpoints, sample size and monthly accrual rate):

# VIII. PERSON COMPLETING CONCEPT SUBMISSION

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| --- | --- | --- | --- |
| Name of Person Completing Form: |  | Date: |  |
| Person Completing Form Address: |  | | |
|  |  | | |
|  |  | | |
| Person Completing Form Phone: |  | | |
| Person Completing Form Fax: |  | | |
| Person Completing Form E-mail: |  | | |
| NOTE: Concepts must be submitted in electronic format by e-mail to PIO@CTEP.NCI.NIH.GOV.  Questions? Please contact the Concept Coordinator at:  Protocol and Information Office, CTEP/DCTD/NCI  Attention: Concept Coordinator  E-mail: [pio@ctep.nci.nih.gov](mailto:loi@tech-res.com)  Phone: (301) 496-1367  Fax: (301) 496-9384 | | | |

1. The NSC Number must be provided if the agent is investigational. See <http://ctep.cancer.gov/protocolDevelopment/codes_values.htm#agent> for a complete list of Organization (Group, Consortium and Institution), IND and NSC Numbers and Disease Names and Codes. [↑](#footnote-ref-1)