**Division of Cancer Prevention**

**CP-CTNet CONCEPT BUDGET SUBMISSION FORM**

***Instructions for filling out this form (please delete all italicized instructions prior to submission):***

1. *Please complete* ***all*** *sections and do not alter the form*
2. *Please use no smaller than 12-point font*
3. *This budget proposal is not intended to be all inclusive, but rather to provide a reasonable estimate of the specified budget categories and anticipated trial cost. A more precise budget will be submitted with the protocol.*

**I. ADMINISTRATIVE INFORMATION**

1. **Submission Date:**
2. **CP-CTNet Lead Academic Organization Name:**
3. **LAO PI:**
4. **Title of Proposal:**
5. **Study PI:**
6. **Expected Duration of Trial:**

*[Expected trial duration should include the total time frame during which CP-CTNet funds will be expended to support trial-related activities]*

**II. BUDGET INFORMATION**

1. **Participant Care Costs (= Complexity Model)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Base Amount** | **Complexity Factor**  | **Cost per Participant** | **# of Participants** | **Total Cost** |
| **Screen 1** | $500  |  |  |  |  |
| **Screen 2** | $750 |  |  |  |  |
| **Intervention** | $2,500 |  |  |  |  |
| **Total Participant Care Costs**  |  |  |  |  |  |

*[Definitions:*

*Screen 1= the costs associated with screening a potential participant to determine eligibility (not including invasive tests and biopsies)*

*Screen 2 = invasive tests and/or biopsies or particularly expensive tests that will only be performed after initial eligibility is determined by Screen 1 (either to further determine eligibility or for baseline biomarker collection/assessment)*

*Intervention = Participant care costs associated with the intervention portion of the trial, including the costs of invasive tests and biopsies performed after the intervention has been initiated (e.g., a follow-up endoscopy would be included in the “Intervention” costs).*

*Complexity Factor = adjustment factor to compensate for more intensive screening or intervention requirements of a particular study.*

*Determine the total cost per participant for Screen 1, Screen 2, and Intervention by multiplying the base amount by the determined Complexity Factor.*

*Determine the total Screen 1, Screen 2, and Intervention Cost by multiplying the Cost per Participant by the # of participants expected to undergo that phase of the study.*

*Total Participant Care Costs are the sum of all Screen 1, Screen 2, and Intervention Costs for all participants undergoing all aspects of the study.]*

1. **Personnel Costs**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Role** | **Institution** | **% Effort/yr** | **Total Cost for all years** |
| **Study PI** |  |  |  |  |
| **Lead Site Coordinator** |  |  |  |  |
| **Other Staff**  |  |  |  |  |
| **Total Personnel Costs** |  |  |  |  |

*[Include all individuals receiving compensation from the CP-CTNet grant - add rows to the table as necessary. If % Effort per year varies by year, note this in the appropriate column (e.g., 10%/yr 1; 5%/yr 2; 0%/yr 3)]*

1. **Biomarkers/Endpoint Analyses**

|  |  |
| --- | --- |
|  | **Total Cost for each marker** |
| **Primary Endpoint** |  |
| **Marker #2** |  |
| **Total Biomarker Costs (for CP-CTNet funding)** |  |

*[List the names of and costs for all the proposed biomarkers that are expected to be paid by the CP-CTNet grant, as well as the summary cost for all biomarkers.]*

1. **Other Major Expenses (e.g., drug purchase costs)**

|  |  |
| --- | --- |
|  | **Total Cost** |
| **Item #1** |  |
| **Total Other Major Expenses** |  |

*[List any major expenses that will be paid by the CP-CTNet grant that are not covered in categories 1-3 above. Examples include purchasing drug or manufacturing matched placebo, if this is not being done by DCP. Insert as many lines as needed; if no additional expenses are expected, indicate “none” in the table.]*

1. **Total Proposed Budget:**

*[Add total costs from Sections 1-4]*

**III. BUDGET JUSTIFICATION**

*[Provide a brief justification for each of the budget categories listed in section II items 1-4, above, in < 2 pages.]*