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|  | **PHASE 1, 2, or 1/2**  **LETTER OF INTENT**  **Submission Form v9.1** |  |
| **National Cancer Institute**  **Division of Cancer Treatment and Diagnosis**  **Cancer Therapy Evaluation Program** | |

*To complete the form electronically, use the mouse pointer or the Tab key to navigate. Select and enter text for each text field.*

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| Lead LAO/Group/Institution1: | [Click and enter Lead LAO/Group; use Institution for non-ETCTN/non-Group trials] | | | |
| Lead LAO/Group/Institution Code1,2: | [Click and enter Lead LAO/Group Code; use Institution Code for non-ETCTN/non-Group trials ONLY] | | | |
| Other LAOs or Trial Team Sites1,2: | [Click and enter other LAOs, other Groups, and any non-LAO/non-Group Clinical Site/Institution Codes; list sites outside USA separately by country. If trial will involve all ETCTN LAOs, write "All ETCTN LAOs" (no codes needed)] | | | |
| Title of LOI : | [Click here to enter Title] | | | |
| LOI Version Submission Date: | [Click here to enter Date of submission to PIO] | | | |
| Agent Information2 *(duplicate rows as needed)*: | Name | NSC # | Source | Investigational? |
| Agent #1: | [Click and enter Agent Name] | [Click and enter NSC] | [CTEP IND, Commercial, or Other] | [Y or N] |
| Agent #2: | [Click and enter Agent Name] | [Click and enter NSC] | [CTEP IND, Commercial, or Other] | [Y or N] |
| Agent #3: | [Click and enter Agent Name] | [Click and enter NSC] | [CTEP IND, Commercial, or Other] | [Y or N] |
| Agent #4: | [Click and enter Agent Name] | [Click and enter NSC] | [CTEP IND, Commercial, or Other] | [Y or N] |
| Tumor Type:  *(Click within the [[ ]] and type ‘x’ to indicate the tumor type)* | [[ ]] Solid Tumor  [[ ]] Hematologic Malignancy (NOS)  [[ ]] Disease-Specific | | | |
| Disease-Specific2:  *(Specify the Name and Code of the Study Disease)* | 1. [Click and enter Disease Name] [Click and enter Disease Code]  2. [Click and enter Disease Name] [Click and enter Disease Code]  3. [Click and enter Disease Name] [Click and enter Disease Code] | | | |
| Phase of Study: | [Click and enter Study Phase] | | | |
| Estimated Monthly Accrual:  *(****Note****: Projected accrual rates should be realistic. Actual accrual will be monitored and measured against this accrual estimate, and failure to meet accrual goals may result in study closure.)* | [Click and enter Accrual] | | | |
| Proposed Sample Size: | Minimum: [Click and enter Size] Maximum: [Click and enter Size] | | | |
| Earliest date the study can begin: | [Click and enter Date] | | | |
| Projected Accrual Dates: | [Click and enter Date] to [Click and enter Date] | | | |

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| Is this study as a whole part of an NIH Grant, Cooperative Agreement or Contract? | [Click and enter Y or N] | | |
| If yes, provide the Award Number: | [Click and enter Award Number] | | |
| Will this study as a whole receive support from non-NCI sources (i.e., industry, foundations)? | [Click and enter Y or N] | | |
| If yes, indicate the source of the funding: | [Click and enter source of non-NCI funding] | | |
| If no, will non-NCI funding be sought? | [Click and enter Y or N] | | |
| Is this a Career Development LOI (CrDL)? | [Click and enter Y or N]  Further information and instructions regarding the submission of a Career Development LOI (CrDL) may be found at <https://ctep.cancer.gov/protocolDevelopment/letter_of_intent.htm>  *Note: If “Y,” provide the mentor’s name below. The CrDL PI and mentor must schedule a call with the IDB agent monitor(s) prior to LOI submission.* | | |
| If yes, please attach and check off the following: | PI curriculum vitae [[ ]]  Institutional letter of commitment [[ ]]  Mentor letter of commitment [[ ]] | | |
| CrDL Mentor Name: | [Click and type Your Full Name to certify the submission] | Date: | [Click and enter Date] |
| CrDL Mentor Street Address: | [Click and enter Room/Suite/Dept.] | | |
|  | [Click and enter Street Address] | | |
|  | [Click and enter City, State, Postal Code] | | |
| CrDL Mentor Phone: | [Click and enter Phone No.] | | |
| CrDL Mentor Fax: | [Click and enter Fax No.] | | |
| CrDL Mentor E-mail: | [Click and enter E-mail Address] | | |

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| The **Investigational Drug Steering Committee** (IDSC) is designed to provide NCI with broad external scientific and clinical input for the design and prioritization of phase 1 and phase 2 trials with agents for which CTEP holds an IND.  Membership of the IDSC includes the Principal Investigators of early phase drug development grants and contracts, representatives from the NCI National Clinical Trials Network (NCTN), NCI staff members, and additional representatives with expertise in biostatistics, correlative science technologies, radiation oncology, etc., as well as patient advocates and community oncologists, as needed. Individuals with special expertise will be included as *ad hoc* members for consideration of specific agents. The current membership list may be found at <https://www.cancer.gov/about-nci/organization/ccct/steering-committees/investigational-drug>.  Note: If the LOI is disapproved by CTEP, the Principal Investigator may appeal the decision by requesting a review by the IDSC. | | | |
| Principal Investigator (PI) Name: | [Click and type Your Full Name to certify the submission] | Date: | [Click and enter Date] |
| PI Street Address: | [Click and enter Room/Suite/Dept.] | | |
| [Click and enter Street Address] | | |
| [Click and enter City, State, Postal Code] | | |
| PI Phone: | [Click and enter Phone No.] | | |
| PI Fax: | [Click and enter Fax No.] | | |
| PI E-mail: | [Click and enter E-mail Address] | | |
| Translational PI Name: | [Click and type Your Full Name to certify the submission] | Date: | [Click and enter Date] |
| Translational PI Address: | [Click and enter Room/Suite/Dept.] |  |  |
| [Click and enter Street Address] |  |  |
| [Click and enter City, State, Postal Code] |  |  |
| Translational PI Phone: | [Click and enter Phone No.] |  |  |
| Translational PI Fax: | [Click and enter Fax No.] |  |  |
| Translational PI E-mail: | [Click and enter E-mail Address] |  |  |
| Study Statistician Name: | [Click and type Your Full Name to certify the submission] | Date: | [Click and enter Date] |
| Statistician Address: | [Click and enter Room/Suite/Dept.] |  |  |
| [Click and enter Street Address] |  |  |
| [Click and enter City, State, Postal Code] |  |  |
| Statistician Phone: | [Click and enter Phone No.] |  |  |
| Statistician Fax: | [Click and enter Fax No.] |  |  |
| Statistician E-mail: | [Click and enter E-mail Address] |  |  |
| Grant PI Name: | [Click and type Your Full Name to certify the submission] | Date: | [Click and enter Date] |
| Grant PI Address: | [Click and enter Room/Suite/Dept.] | | |
|  | [Click and enter Street Address] | | |
|  | [Click and enter City, State, Postal Code] | | |
| Grant PI Phone: | [Click and enter Phone No.] | | |
| Grant PI Fax: | [Click and enter Fax No.] | | |
| Grant PI E-mail: | [Click and enter E-mail Address] | | |
| Group Chair-PI (GC-PI) Name: | [Click and type Your Full Name to certify the submission] | Date: | [Click and enter Date] |
| GC-PI Address: | [Click and enter Room/Suite/Dept.] | | |
| [Click and enter Street Address] | | |
| [Click and enter City, State, Postal Code] | | |
| GC-PI Phone: | [Click and enter Phone No.] | | |
| GC-PI Fax: | [Click and enter Fax No.] | | |
| GC-PI E-mail: | [Click and enter E-mail Address] | | |
| The Principal Investigator agrees to accept Confidential Information, such as the Investigator Brochure and any other shared information, and employ all reasonable efforts to maintain the Confidential Information secret and confidential, such efforts to be no less than the degree of care employed by the Principal Investigator/Institution (the receiving Party) to preserve and safeguard its own confidential information. The Confidential Information of the NCI (the disclosing Party) shall not be disclosed, revealed, or given to anyone by the receiving Party except individuals working on behalf of the receiving Party who are under an obligation of confidentiality to the receiving Party and who have a need to review the Confidential Information in connection with the receiving Party's evaluation. Such individuals shall be advised by the receiving Party of the confidential nature of the Confidential Information and that the Confidential Information shall be treated accordingly. By submission of this Letter of Intent Submission Form, the Principal Investigator agrees to this statement. | | | |
| Please submit LOIs to the Protocol Information Office (PIO) via e-mail at:  [**pio@ctep.nci.nih.gov**](mailto:pio@ctep.nci.nih.gov)**, Attention: LOI Coordinator**  **Notes**: LOIs from a NCTN Group must be submitted through the Group Operations.  Proposals for trials to be conducted under a Cooperative Agreement must include complete contact information for the Principal Investigator and Protocol Chair.  EDDOP investigators and CrDL investigators/mentors must schedule a call with the IDB agent monitor(s) prior to LOI submission. All other investigators are encouraged to schedule a call before LOI submission.  Questions? Please e-mail the LOI Coordinator at [pio@ctep.nci.nih.gov](mailto:PIO@CTEP.NCI.NIH.GOV). | | | |

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| **Rationale and Background:** *(This section should provide the study rationale and supporting preclinical and/or clinical data and also address the following: what is the unmet need, why the patient population was chosen, why the drug or drug combination was chosen and any potential safety concerns with the drugs or drug combination, and how the study results might impact future trials/practice. Preclinical data supporting the proposed study should be presented, and not merely referenced. The background information should be limited to what is relevant to the proposed study and should be presented succinctly but with sufficient detail to enable evaluation by the reviewers. Avoid indiscriminate cutting-and-pasting from investigator brochures, trial solicitations, or other CTEP communications.)*  [Click and enter Background] |
| **Hypotheses:** *(Succinctly state the hypothesis for each primary and secondary objective.)*  [Click and enter Rationale/Hypotheses] |
| **Objectives:** *(List primary and secondary objectives. Ensure that the study design allows for these objectives to be met and that the statistical plan provides an adequate plan to analyze or describe the data for each objective.)*  [Click and enter Objectives] |
| **Abbreviated Eligibility Criteria:** *(Provide key inclusion criteria. These should include patient age, performance status, whether abnormal organ function is permitted [if Yes, list only abnormal organ function parameters], permissible and required prior therapy, tumor type, and integral markers, if applicable.)*  [Click and enter Eligibility Criteria] |
| **Study Design:** *(Succinctly describe the general study design. If applicable, describe randomization and/or stratification. A schema or flow diagram may be used, if appropriate. If the trial involves biomarker studies, the Biomarkers Tables below* ***must*** *be filled out according to the instructions. Appendices detailing the biomarker assays may be required as well. Please read the instructions carefully.)*  [Click and enter Study Design] |
| **Treatment Plan:** *(State the dose, method of administration, and schedule of each drug, and, if phase 1, provide the dose escalation scheme, and definitions of DLTs. State the duration of treatment, the duration of the study, and the duration of follow-up.)*  [Click and enter Plan] |

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| **Correlates:** *For* ***all*** *correlates, whether integral, integrated, or exploratory, and whether or not CTEP funding support will be requested (through the agent CRADA), provide text in an appendix describing them and complete the* ***Biomarkers and Specimen Collection Tables*** *below. Definitions of integral and integrated biomarker studies are also provided below. All other biomarker tests are considered exploratory. In the Biomarker table, provide the name of the laboratory PI for each correlate and his/her site and email address. In the column labeled “Mandatory or Optional”, indicate with “M” or “O” if specimen collection or imaging test is either* ***M****andatory or* ***O****ptional. If the assay result will be reported to the patient or the patient’s physician at any time, on or off study, the assay must be performed at a CLIA-approved laboratory. In the Specimen Collection table, provide details about the type and quantity of the specimen(s) to be collected for the correlative studies outlined in the Biomarker table.*  *For all correlates, provide a* ***letter of commitment*** *from the collaborating laboratory. If an outside company will be contracted to perform the assay, please clearly state the company name as the assay laboratory.*  *Integral studies are defined as assays/tests that must be performed in order for the trial to proceed. Integral studies are inherent to the design of the trial from the outset and must be performed in real time for the conduct of the trial. Examples include tests to determine eligibility, tests to assign treatment or stratify randomization, and tests whose results serve as the primary endpoint of the trial. Integral biomarkers may require a CLIA-certified laboratory, which will be needed if the test results will be returned to the patient or their physician.*  *An integral assay that will be used to determine eligibility or treatment may need to be performed under an Investigational Device Exemption (IDE) from the FDA.*  *Integrated studies are defined as assays/tests that are clearly identified as part of the clinical trial from the outset and are intended to address the highest priority scientific question in the trial. Integrated studies in general should be performed on all the trial participants or on a pre-defined subset such as an expansion cohort. Plans for specimen collection, laboratory measurements, use of cutpoints, and statistical analysis should be pre-specified and should be based on sufficient preliminary data to ensure scientifically valid results from the trial.*  **Biomarker Review Committee (BRC) Requirements:** *With the current emphasis on biomarker-driven drug development, it is necessary to ensure that fit-for-purpose assays of these biomarkers are incorporated in CTEP-sponsored protocols. To that end, the NCI Division of Cancer Treatment and Diagnosis (DCTD) has formed the Biomarker Review Committee (BRC), which is now responsible for reviewing the biomarker components of CTEP-sponsored clinical trials. Specifically, LOIs for trials that are not reviewed by an NCI disease-specific steering committee will require BRC review and approval if they meet* ***any*** *of the following criteria:*   * *Integral or integrated biomarkers* * *ETCTN funds are requested for sample collection and/or performance of the assay (****a budget must be provided****)* * *Requires biopsies that are mandatory specifically for the purpose of a biomarker assay* * *Procedure is burdensome on the patient (invasiveness, schedule, etc.)*   *The BRC may also, at its discretion, review any assay judged to be of particular importance to the trial. To expedite BRC review, please complete the* ***Study Checklist for CTEP-Supported Early Phase Trials with CTEP-Supported Biomarker Assays*** *[at:*  <http://ctep.cancer.gov/protocolDevelopment/docs/Study_Checklist_Early_Phase_Trials_Biomarker_Assays.docx>*]* *for all assays that meet any of these criteria, and submit the completed checklist(s) as an* ***appendix*** *to this LOI. In lieu of completing checklist items 5-6, the* ***biomarker assay templates*** *available at* <https://cdp.cancer.gov/scientific_programs/pacct/templates.htm> *may be utilized.*  ***(Note: For LOI review, each biomarker assay intended for inclusion in the study must be entered into the Biomarkers and Specimen Collection tables below, and all fields must be completed, regardless of whether BRC review will be needed.)***  **Biomarkers Table\***   | **Priority** | **Biomarker Name a** | **Assay**  **(CLIA: Y/N)** | **Use in the Trial (Integral, Integrated, or Exploratory) AND Purpose b** | **Specimens Tested** | **Collection Time Points** | **Mandatory or Optional** | **Assay Laboratory and Lab PI c** | **Funding Source(s) d** | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Tissue-based Biomarkers** | | | | | | | | | | 1 | [Click and enter Biomarker(s)] | [Click and enter Assay]  CLIA: | [Click and enter Use]  [Click and enter Purpose] | [Click and enter Tissue] | [Click and enter Time Points] | [M/O] | [Click and enter Assay Lab/Lab PI]  [Click and enter Lab PI e-mail address for BRC correspondence] | [Click and enter Funding Source] | | 2 | [Click and enter Biomarker(s)] | [Click and enter Assay]  CLIA: | [Click and enter Use]  [Click and enter Purpose] | [Click and enter Tissue] | [Click and enter Time Points] | [M/O] | [Click and enter Assay Lab/Lab PI]  [Click and enter Lab PI e-mail address for BRC correspondence] | [Click and enter Funding Source] | | **Blood-based Biomarkers** | | | | | | | | | | 1 | [Click and enter Biomarker(s)] | [Click and enter Assay]  CLIA: | [Click and enter Use]  [Click and enter Purpose] | [Click and enter Fluid] | [Click and enter Time Points] | [M/O] | [Click and enter Assay Lab/Lab PI]  [Click and enter Lab PI e-mail address for BRC correspondence] | [Click and enter Funding Source] | | 2 | [Click and enter Biomarker(s)] | [Click and enter Assay]  CLIA: | [Click and enter Use]  [Click and enter Purpose] | [Click and enter Fluid] | [Click and enter Time Points] | [M/O] | [Click and enter Assay Lab/Lab PI]  [Click and enter Lab PI e-mail address for BRC correspondence] | [Click and enter Funding Source] | | ***[Click and enter Other Specimen]*** | | | | | | | | | | 1 | [Click and enter Biomarker(s)] | [Click and enter Assay]  CLIA: | [Click and enter Use]  [Click and enter Purpose] | [Click and enter Tissue/Fluid] | [Click and enter Time Points] | [M/O] | [Click and enter Assay Lab/Lab PI]  [Click and enter Lab PI e-mail address for BRC correspondence] | [Click and enter Funding Source] |   *\* Insert additional rows as needed.*  *a Multiple biomarkers may be listed in the same row if they are performed using the same assay in the same laboratory by the same investigator. This field may also specify a panel (e.g., BROCA); individual markers in the panel may be listed in Appendix B.*  *b Briefly specify the role of the biomarker in the study (e.g., eligibility criterion, assignment to treatment, stratification factor, response assessment, prospective research, hypothesis generation, etc.). If a hypothesis will be tested, please succinctly state it (e.g., “to identify biomarkers of response”).*  *c If an outside company will be contracted to perform the assay, please enter the company name under Assay Lab.*  *d Indicate all funding sources. Specify whether company funding (either through CTEP CRADA or directly from the company) is requested for the sample (tissue/fluid) collection, for the assay, or both. If CTEP CRADA funding is requested, please provide a budget.* |
| **Specimen Collection Table\***   | **Specimen Type** | **Intended Assay(s)** | **Archival** | **Baseline** | **[Click and enter Time Point]** | **[Click and enter Time Point]** | **[Click and enter Time Point]** | **[Click and enter Time Point]** | | --- | --- | --- | --- | --- | --- | --- | --- | | **Archival Specimens** | | | | | | | | | [Click and enter Specimen Type, e.g., Tumor/FFPE] | [Click and enter assay(s) that will use this specimen. If >1, list priority] | [Click and enter quantity, e.g., # of slides (select one: Optional or Mandatory)] | N/A | N/A | N/A | N/A | N/A | | **Core Biopsy Specimens** a | | | | | | | | | [Click and enter post-biopsy specimen processing type, e.g., Formalin] | [Click and enter assay(s) that will use this specimen. If >1, list priority] | N/A | [Click and enter core biopsy priority, e.g., Core Biopsy #1 (select one: Optional or Mandatory)] | [Click and enter core biopsy priority, e.g., Core Biopsy #1 (select one: Optional or Mandatory)] | [Click and enter core biopsy priority, e.g., Core Biopsy #1 (select one: Optional or Mandatory)] | [Click and enter core biopsy priority, e.g., Core Biopsy #1 (select one: Optional or Mandatory)] | [Click and enter core biopsy priority, e.g., Core Biopsy #1 (select one: Optional or Mandatory)] | | [Click and enter post-biopsy specimen processing type, e.g., Frozen] | [Click and enter assay(s) that will use this specimen. If >1, list priority] | N/A | [Click and enter core biopsy priority, e.g., Core Biopsy #2 (select one: Optional or Mandatory)] | [Click and enter core biopsy priority, e.g., Core Biopsy #2 (select one: Optional or Mandatory)] | [Click and enter core biopsy priority, e.g., Core Biopsy #2 (select one: Optional or Mandatory)] | [Click and enter core biopsy priority, e.g., Core Biopsy #2 (select one: Optional or Mandatory)] | [Click and enter core biopsy priority, e.g., Core Biopsy #2 (select one: Optional or Mandatory)] | | [Click and enter post-biopsy specimen processing type, e.g., Formalin] | [Click and enter assay(s) that will use this specimen. If >1, list priority] | N/A | [Click and enter core biopsy priority, e.g., Core Biopsy #3 (select one: Optional or Mandatory)] | [Click and enter core biopsy priority, e.g., Core Biopsy #3 (select one: Optional or Mandatory)] | [Click and enter core biopsy priority, e.g., Core Biopsy #3 (select one: Optional or Mandatory)] | [Click and enter core biopsy priority, e.g., Core Biopsy #3 (select one: Optional or Mandatory)] | [Click and enter core biopsy priority, e.g., Core Biopsy #3 (select one: Optional or Mandatory)] | | **Other Specimens** | | | | | | | | | [Click and enter Specimen Type, e.g., Blood/Streck cell-free DNA tube] | [Click and enter assay(s) that will use this specimen. If >1, list priority] | N/A | [Click and enter quantity, e.g., 1 x 10 mL (select one: Optional or Mandatory)] | [Click and enter quantity, e.g., 1 x 10 mL (select one: Optional or Mandatory)] | [Click and enter quantity, e.g., 1 x 10 mL (select one: Optional or Mandatory)] | [Click and enter quantity, e.g., 1 x 10 mL (select one: Optional or Mandatory)] | [Click and enter quantity, e.g., 1 x 10 mL (select one: Optional or Mandatory)] | | [Click and enter Specimen Type, e.g., Blood/green-top tube] | [Click and enter assay(s) that will use this specimen. If >1, list priority] | N/A | [Click and enter quantity, e.g., 3 x 10 mL (select one: Optional or Mandatory)] | [Click and enter quantity, e.g., 3 x 10 mL (select one: Optional or Mandatory)] | [Click and enter quantity, e.g., 3 x 10 mL (select one: Optional or Mandatory)] | [Click and enter quantity, e.g., 3 x 10 mL (select one: Optional or Mandatory)] | [Click and enter quantity, e.g., 3 x 10 mL (select one: Optional or Mandatory)] | | [Click and enter Specimen(s)] | [Click and enter assay(s) that will use this specimen. If >1, list priority] | N/A | [Click and enter quantity] | [Click and enter quantity] | [Click and enter quantity] | [Click and enter quantity] | [Click and enter quantity] |   N/A=not applicable  *\** ***This table must identify how each individual specimen to be collected in this study will be used.*** *Insert additional rows or columns as needed. Grouping frequent time points with the same collection quantity (*e.g.*, blood for pharmacokinetic assays) is permitted.*  *a* ***Core biopsy priority (1-6) should be entered under relevant time point. The biopsy requirement and order of core biopsy importance could be different at different time points. If no core biopsies are to be collected at a time point, leave the cell empty.***  *An Interventional Radiologist (defined as a Radiologist responsible for acquisition of biopsy specimens) should be consulted during the initial preparation of the LOI involving any core biopsy procedures and to assure that a system is in place for patient assessment and consultation prior to undergoing a procedure to obtain tissue specimens.*  *Notes:*  *Cores 1 & 2-are obtainable in most circumstances and settings based on risk assessment (for lesions with pre-biopsy scores of 2-3)*  *Cores 3 & 4-are obtainable in some circumstances based on safety and risk assessment (for lesions with pre-biopsy scores of 2-3)*  *Cores 5 & 6-are RARELY obtainable based on safety and risk assessment, including lesion size and location* |
| **Imaging Correlates Table\***   | **Correlative Objective**  **(Name of Correlate & Lead PI and Site)** | **Imaging Technique** | **Organ(s) Scanned and Timing of Scans** | **Mandatory or Optional** | | --- | --- | --- | --- | |  |  |  |  | |  |  |  |  | |  |  |  |  |   *\* Insert additional rows as needed* |
| **Endpoints/Statistical Considerations:** *(State explicitly the null and alternative hypothesis(es) for the primary objective(s). Also state the sample size and associated type I and type II errors. Provide an analysis plan for both primary and secondary objectives, including correlatives. Include information about which statistical tests will be applied. State the projected accrual rate and ensure that the accrual goals are realistic and achievable with current resources. If the trial will be an ETCTN trial involving 3 or fewer LAOs, then this proposal’s accrual goals must be supported by letters of commitment from each participating institution [see* ***Appendix A****].)*  [Click and enter Endpoints] |
| **References:** *(Provide references for cited data and key background/concepts. Verify all references.)*  [Click and enter References] |

**Appendix A –Institutional Letters of Commitment for Projected Accrual & Competing Trials**

***Instructions:***

*If the proposed trial will involve 3 or fewer ETCTN LAOs, the following must be provided:*

1. *Letters of commitment must be provided by each participating institution to support the proposed accrual goals. Each letter must provide a reasonable estimate of the number of patients that the institution will enroll to this trial.*
2. *Complete the “Competing Trials Table” below.*

*The LOI and all letters of commitment must be submitted to the lead (corresponding) LAO for review and sign-off prior to the lead (corresponding) LAO submitting the LOI and letters of commitment to PIO.*

*If the study fails to achieve at least 50% of its planned accrual rate by the second quarter, CTEP may, at its discretion, issue a request for a Corrective Action Plan (CAP) and/or open the trial across the ETCTN. For more details, please see the most recent Early Phase Trial Slow Accrual Guidelines at* [*https://ctep.cancer.gov/protocolDevelopment/cde\_data\_policies.htm*](https://ctep.cancer.gov/protocolDevelopment/cde_data_policies.htm) *.*

*If this study will involve more than 3 ETCTN LAOs or is a Group (*e.g.*, Alliance, ECOG-ACRIN) trial, please write “*Not applicable*” below.*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Competing Trials:** *If this trial will involve 3 or fewer ETCTN LAOs, list all Active, Approved, or In Review studies at the Lead (coordinating) LAO for which this patient population will be eligible (active trials should also be listed under documented accrual). To provide data on additional trials, insert additional rows as needed.*  **Competing Trials Table\***   | **Protocol Number / Title / Sponsor/ Relevant Site only**  ***(Include NCI Number if NCI-sponsored)*** | **Trial Activation Date** | **Anticipated Completion Date** | **No. of Patients Enrolled to Date / Patient Enrollment Period /  Duration of Patient Enrollment /  Total planned Patient Enrollment**  ***(Only include patients enrolled at site(s) relevant to LOI proposal.)*** | | --- | --- | --- | --- | | [Click and enter Number] */* [Click and enter Title]/ [Click and enter Sponsor / [Click and enter Relevant Site Name]] | [Click and enter Activation Date] | [Click and enter Anticipated Completion Date] | [Click and enter Patients Enrolled] /  [Click and enter Enrollment Start Date] to [Click and enter Enrollment End Date] /  [Click and enter the Number of Months of Enrollment] /  [Click and enter Planned Enrollment] |   *\* Insert additional rows as needed.* |

**Appendix B – Correlative and Biomarker Assay Description(s)**

*Details of biomarker assays may be provided here.*

*For all integral and integrated biomarkers and for any exploratory biomarkers for which CTEP support is requested for sample collection or performance of the assay, state experience with the assay and assay methods, performance, operating characteristics, and whether the assay will be performed in a CLIA-approved laboratory. Please use the Study Checklist for CTEP-Supported Early Phase Trials with CTEP-Supported Biomarker Assays at:* <http://ctep.cancer.gov/protocolDevelopment/docs/Study_Checklist_Early_Phase_Trials_Biomarker_Assays.docx>*. In lieu of completing checklist items 5-6, the biomarker assay templates available at* <https://cdp.cancer.gov/scientific_programs/pacct/templates.htm> *may be utilized.*