



**PHASE I, II, or I/II
LETTER OF INTENT
Submission Form v2.0**

**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. To easily see text fields, go to **Tools|Options** from Word's menu, click the **View** tab, and in the **Show** block select **'Always'** from the **Field Shading** drop down list.

Lead Group/Institution: [Click here to enter Organization]	
Lead Institution/Group CTEP ID: ¹ [Click here to enter Group/Institution Code]	
Other Institutions/Groups on study: [Click here to enter other Organizations]	
Title of LOI: [Click here to enter Title]	
Lead Agent supplied by NCI: ¹ [Click here to enter Agent]	
Other Agents supplied by NCI: [Click here to enter other Agents]	
Commercial Agents in Study: [Click here to enter Commercial Agents]	
Tumor Type: <input type="checkbox"/> Solid Tumor <i>(Click within the <input type="checkbox"/> and type 'x' to indicate the tumor type)</i> <input type="checkbox"/> Hematologic Malignancy (NOS) <input type="checkbox"/> Disease-Specific	
Disease-Specific: ¹ <i>(Specify the Name and Code of the Study Disease)</i>	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]
Performance Status: [Click and enter Status]	
Abnormal Organ Function Permitted? [Click and enter Y or N]	
Prior Therapy: [Click and enter Prior Therapy]	
Phase of Study: [Click and enter Study Phase]	
Treatment Plan: [Click and enter Plan]	
Rationale/Hypothesis: [Click and enter Rationale]	
Laboratory Correlates: [Click and enter Lab]	
Endpoints/Statistical Considerations: [Click and enter Endpoints]	
Estimated Monthly Accrual: [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: Start: [Enter Month] / [Enter Year] End: [Enter Month] / [Enter Year] <i>(Month/Year format)</i>	

¹ Detailed Institution, Group, Agent NSC, and Disease codes are available on the CTEP Home Page at <http://ctep.cancer.gov/guidelines/values.html>

<p>To document accrual rate, list trials with patients who had similar Tumor Type/Phase of Study/Prior Therapy:</p> <p>Protocol Number / Title / Sponsor : [Click and enter Number] / [Click and enter Title] / [Click and enter Sponsor] <i>(Include NCI Number if NCI-sponsored)</i></p> <p>Trial Activation / Trial Completion Dates: [Click and enter Activation Date] / [Click and enter Completion Date]</p> <p>No. of Patients Enrolled:* [Click here to enter Pt. Number] <i>(*Entire study or to date, if study is not completed. Only include patients enrolled at site(s) relevant to LOI proposal)</i></p>	
<p>List all Active, Approved, or In Review studies at your institution for which this patient population will be eligible:</p> <p>Protocol Number / Title / Sponsor: [Click and enter Number] / [Click and enter Title] / [Click and enter Sponsor] <i>(Include NCI Number if NCI-sponsored)</i></p> <p>Trial Activation Date / Anticipated Completion Date: [Click and enter Activation Date] / [Click and enter Anticipated Completion Date]</p> <p>No. of Patients Enrolled to Date / Patient Enrollment Period / Duration of Patient Enrollment / Total planned Patient Enrollment:* [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] <i>(*Only include patients enrolled at site(s) relevant to LOI proposal)</i></p>	
<p>Is this LOI part of an NIH Grant, Cooperative Agreement or Contract? [Click and enter Y or N]</p> <p>If yes, provide the Award Number: [Click and enter Award Number]</p>	
<p>Will this study receive support from non-NCI sources (i.e., industry, ACS)? [Click and enter Y or N]</p>	
<p>If the proposed trial includes correlative studies, CTEP assumes funding is available to support them.</p> <p>If yes, is it Grant funding? [Click and enter Y or N]</p> <p>If yes, provide the Grant Number: [Click and enter Grant Number] <i>(Attach budget request to e-mail or send hard copy)</i></p> <p>If no, is Translational Research Initiative (TRI) requested? [Click and enter Y or N] <i>(If yes, complete the PHS 398 budget template to submit budget proposal. PHS 398 is available from http://www.aecom.yu.edu/ogs/Guide/subproposals.htm)</i> <i>(TRI previously referred to as TRF)</i></p> <p>If no, please explain: [Click and enter explanation]</p>	
<p>Principal Investigator (PI) Name: [Click and enter Name]</p> <p>PI Signature: _____ Date: _____</p> <p>PI Street Address: [Click and enter Room/Suite/Dept.] [Click and enter Street Address] [Click and enter City, State, Postal Code]</p> <p>PI Phone: [Click and enter Phone No.]</p> <p>PI Fax: [Click and enter Fax No.]</p> <p>PI E-mail: [Click and enter E-mail Address]</p>	
<p>Group Chair/Cooperative Agreement-PI (GCCA-PI) Name: [Click and enter Name]</p>	

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GCCA-PI Signature: _____ Date: _____

GCCA-PI Address: [Click and enter Room/Suite/Dept.]
[Click and enter Street Address]
[Click and enter City, State, Postal Code]

GCCA-PI Phone: [Click and enter Phone No.]

GCCA-PI Fax: [Click and enter Fax No.]

GCCA-PI E-mail: [Click and enter E-mail Address]

Non Group Grant-PI Name: [Click and enter Name]

Non Group Grant-PI Signature: _____ Date: _____

Non Group Grant-PI Address: [Click and enter Room/Suite/Dept.]
[Click and enter Street Address]
[Click and enter City, State, Postal Code]

Non Group Grant-PI Phone: [Click and enter Phone No.]

Non Group Grant-PI Fax: [Click and enter Fax No.]

Non Group Grant-PI E-mail: [Click and enter E-mail Address]

Please submit Letter of Intent forms (LOIs) to the Protocol and Information Office (PIO) via e-mail at:

pio@ctep.nci.nih.gov, Attention: LOI Coordinator

Notes: LOIs from Cooperative 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.

Questions? Please call LOI Coordinator at (301) 496-1367.

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