PRC New Study Cover Sheet for Non-CTO Managed Trials

### Required Documents for Submission

1. PRC New Study Cover Sheet.
2. Clinical Protocol (use UNC Lineberger template if UNC Lineberger is the sponsor of an IIT).
3. Investigator Brochures (for Non-FDA-approved drugs, or FDA-approved drugs used in a novel setting).
4. [Biostatistician Sign-Off](https://www.unclineberger.org/protocolreview/new-studies/biostat-signoff) (for studies in which UNC Lineberger is the sponsor).
5. Questionnaires /Surveys/Instruments (when applicable).
6. Recruitment Material (when applicable).
7. Sign-Off on PRC New Study Cover Sheet from relevant Disease Group Leader for any UNC cancer populations who will be recruited for this study.

### Protocol

1. Protocol Number:
2. Title:
3. Sponsor:
4. IRB Number:
5. Type of Research (please circle or highlight one):
	1. **Interventional** (Individuals assigned by investigator to receive specific interventions. Participants may receive diagnostic, therapeutic, behavioral or other types of interventions.)
	2. **Observational** (Research on cancer patients and healthy populations that involves no intervention (behavioral, diagnostic, therapeutic or otherwise) or alteration in status of participants.)
	3. **Ancillary** (Stimulated by, but not a required part of, main clinical trial, and utilizes patient or other resources of main trial to generate information relevant to it. Must be linked to an active clinical research study.)
	4. **Correlative** (Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc.)
6. Type of Protocol (please circle or highlight one):
	1. [**Treatment**](#Treatment) (Designed to evaluate one or more interventions for treating a disease, syndrome or condition. Note: Also known as therapeutic trials.)
	2. **Diagnostic** (Designed to evaluate one or more interventions aimed at identifying disease or health condition.)
	3. **Health Services**

 **Research** (Designed to evaluate delivery, processes, management, organization or financing of health care.)

* 1. **Prevention** (Designed to assess one or more interventions aimed at preventing development of a specific disease or health condition.)
	2. **Screening** (Designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition or risk factor.)
	3. **Basic Science** (Designed to examine basic mechanisms of action (e.g., physiology, biomechanics) of an intervention.)
	4. **Supportive Care** (Designed to evaluate one or more interventions where primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in participant’s health or function. In general, intervention is not intended to cure disease.)
	5. [**Other**](#Other) (Not in other categories.)

### Phases of Trial

1. Does this study encompass more than one phase (e.g., Phase I/II, Phase Ib/II, etc.)? (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. If so, please indicate in which phases UNC will be participating: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. **Data and Safety Monitoring Plan**
4. Does the protocol provide a well-documented data and safety monitoring plan? (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. If yes, please indicate the section and page number where it can be found in the protocol: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. If not, please provide supporting documentation, such as a DSM charter or an email from the sponsor delineating plans for data and safety monitoring.
7. If DSM is discussed in the protocol but a separate document, such as a DSM charter, is also referenced in the protocol, please provide a copy.

### Institutional Conflict of Interest (COI) for All Trials

Institutional Conflicts of Interest are situations where a potential or existing financial interest relationship between the University and an external entity comprises the integrity of the institutional decision-making. An Institutional COI review generally occurs when:

* University licensed Intellectual Property is being used in a human treatment study.
* The University is manufacturing the drug or device being used in a human study.
* An entity in which the University owns equity or has a financial interest is the sponsor, particularly for a human study.
* The donor sponsoring a gift supporting a study also has an interest in the data results.

(For additional information: UNC Research Conflict of Interest website (<https://research.unc.edu/compliance/coi/>).)

1. Are there any Institutional COIs associated with this study? (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### Information on Specimens for UNC Lineberger IITs Only (This includes registries that involve specimens)

Does the study incorporate an integrated or an integral biomarker? (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If yes, please answer the following questions:

1. In which lab will the research be conducted? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Please indicate the section and page number where the honest broker plan can be found in the protocol: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Is the research being conducted under Clinical Laboratory Improvement Amendments (CLIA?) (Y/N) \_\_\_\_\_\_\_\_\_
4. Is there a plan to return results to subjects? (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. Please provide the section and page number of the protocol where information can be found regarding what steps will be taken to ensure samples are deidentified: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### Genomic Data for UNC Lineberger IITs Only

UNC Lineberger’s Office of Genomics Research can assist with determining how and where to deposit a study’s human genomic data when required by funding organization or journal. The submission process can delay manuscript submission so early engagement with OGR is recommended.

1. Does this protocol involve genomics research? (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If yes, it is recommended that the study team contact the Office of Genomics Research at ogr@unc.edu for more information on this data requirement.

### Accrual for UNC Lineberger sponsored IIT single site trials

|  |  |  |
| --- | --- | --- |
| Accrual Information | Explanation | Number |
| Protocol Target Accrual | Total expected number of subjects to meet study objectives [This number may be found in the Statistical Section of the protocol. If not present, consult with the Biostatistician and/or the PI.] |  |
| Total Accrual Goal (Lower) | Total expected number of subjects to meet study objectives [This number may be found in the Statistical Section of the protocol. If not present, consult with the Biostatistician and/or the PI.] |  |
| Total Accrual Goal (Upper) | Total expected number of subjects to *recruit* to meet Total Accrual Goal (Lower) [This number may be found in the Statistical Section of the protocol. If not present, consult with the Biostatistician and/or the PI.] |  |
| Annual Accrual Goal | UNC accrual goal on a yearly basis |  |
| Accrual Duration | Estimated number of months trial will be open to accrual |  |

### Accrual for UNC Lineberger sponsored IIT multicenter trials

|  |  |  |
| --- | --- | --- |
| Accrual Information | Explanation | Number |
| Protocol Target Accrual | Total expected number of subjects to meet study objectives [This number may be found in the Statistical Section of the protocol. If not present, consult with the Biostatistician and/or the PI.] |  |
| Total Accrual Goal (Lower) | Total expected number of *UNC subjects* to meet study objectives [This number may be found in the Statistical Section of the protocol. If not present, consult with the Biostatistician and/or the PI.] |  |
| Total Accrual Goal (Upper) | Total expected number of subjects to *recruit* to meet Total Accrual Goal (Lower) [This number may be found in the Statistical Section of the protocol. If not present, consult with the Biostatistician and/or the PI.] |  |
| Annual Accrual Goal | UNC accrual goal on a yearly basis |  |
| Accrual Duration | Estimated number of months trial will be open to accrual |  |
| Affiliate Accrual Goal | Number of subjects that will accrue at affiliate sites only |  |
| Number of planned sites | Number of sites, excluding UNC |  |

### Accrual for all other trials

|  |  |  |
| --- | --- | --- |
| Accrual Information | Explanation | Number |
| Protocol Target Accrual | Number of subjects to accrue for protocol at UNC |  |
| Total Accrual Goal (Lower) | Total expected number of subjects to be *accrued* at UNC |  |
| Total Accrual Goal (Upper) | Total expected number of subjects to be *recruited* at UNC |  |
| Annual Accrual Goal | UNC accrual goal on a yearly basis |  |
| Accrual Duration | Estimated number of months trial will be open to accrual |  |

### University Clinical Research Trainees – UNC Lineberger IITs Only

The PRC allows University clinical research trainees to attend PRC meetings in order to observe the PRC process, after signing an appropriate confidentiality agreement.

1. Does the PI of this study give permission for either a University clinical research trainee or their faculty advisor to either observe the discussion of this study during a PRC meeting or review the protocol? (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_

### Management Group

Please indicate which UNC department will manage this study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### IND/IDE for All Trials Which Are Not UNC Lineberger Investigator Initiated Trials

1. Is there an IND involved? (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Is there an IDE involved? (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### IND/IDE for UNC Lineberger Investigator Initiated Trials

1. If this is a UNC Lineberger Investigator Initiated trial, is there an Investigational New Drug (IND) or Investigational Device (IDE) involved?  (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Please refer to the IND Exemption Checklist located on the PRC website.  For additional assistance, please contact the CPO Clinical Development team at LCCC\_IND@unc.edu.)

1. If the study involves an IND but the team believes the study is exempt from filing an IND with the FDA, please review the IND Exemption Checklist (located on the PRC website) and provide an IND Exemption Letter.  (Contact the CPO Clinical Development team at LCCC\_IND@unc.edu for assistance with this letter.)
2. If the study involves an IDE but the team believes the study is exempt from filing an IDE with the FDA, please provide a copy of the completed Investigational Device Worksheet to be filed with the IRB application.
3. If the study involves an IND/IDE and the team is currently working on the submission, please indicate the current status of the IND/IDE process:

\_\_\_\_\_\_\_\_\_\_ FDA submission currently being drafted.

\_\_\_\_\_\_\_\_\_\_ FDA submission in 30-day wait period or being redrafted with revisions requested by FDA.

\_\_\_\_\_\_\_\_\_\_ IND/IDE submitted and approved by FDA.

### Primary Completion Date

Please provide the primary completion date for the study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(For UNC Lineberger IITs, this date is the time point estimated to complete the primary endpoints. For all other studies, this date can be found in the protocol or on ClinicalTrials.gov.)

### Accrual of Racial and Ethnic Groups Underrepresented in Biomedical Research

It is the goal of UNC Lineberger to have at least 20% accrual of underrepresented racial/ethnic groups (defined by the NIH as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders).  If this is a treatment trial, does the team anticipate any difficulty in reaching this benchmark?

[ ]  No [ ]  Yes

If the answer is yes, please note that this cover sheet will be shared with the EQUITY in Clinical Trials Initiative staff to assess opportunities to facilitate recruitment of underrepresented racial/ethnic groups in this study.

1. **Staff**
2. Name of Principal Investigator\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Check names of Co-investigators. If the Co-Investigators are not listed, add them at the end of the last column. **Please ensure all Co-Investigators identified with the IRB are listed below and have been added to OnCore**.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Medical Oncologists |  |  | Medical Oncologists (cont.) |  |  | Pediatric Oncologists |
|  | Yara Abdou |  |  | Benjamin Vincent |  |  | Yasmina Abajas |
|  | Paul Armistead |  |  | Jared Weiss |  |  | Thomas Alexander |
|  | Ethan Basch |  |  | Young Whang |  |  | Jacquelyn Baskin-Miller |
|  | Anne Beaven |  |  | William (Bill) Wood |  |  | Julie Blatt |
|  | Lisa Carey |  |  | Joshua Zeidner |  |  | Maria Boucher |
|  | Marjory Charlot |  |  |  |  |  | Jennifer Brondon |
|  | James Coghill |  |  | **Surgical Oncologists** |  |  | Ian Davis |
|  | Frances Collichio |  |  | Jeffrey Blumberg |  |  | Stuart Gold |
|  | Claire Dees |  |  | Jeremiah Deneve |  |  | Catherine Habashy |
|  | Christopher Dittus |  |  | Matt Ewend |  |  | John Hipps |
|  | Shakira Grant |  |  | Kristalyn Gallagher |  |  | George Hucks |
|  | Natalie Grover |  |  | Elizabeth Gleeson |  |  | Kimberly Kasow |
|  | Katarzyna Jamieson |  |  | Trevor Hackman |  |  | David Kram |
|  | Caron Jia |  |  | Hong Jin Kim |  |  | Gerardo Quezada |
|  | William Kim |  |  | Lawrence Kim |  |  | Barbara Savoldo |
|  | Carrie Lee |  |  | Michael LeCompte |  |  | Andrew Smitherman |
|  | Eben Lichtman |  |  | Catherine Lumley |  |  | Patrick Thompson |
|  | Brian Miller |  |  | Michael Meyers |  |  | Kate Westmoreland |
|  | Matthew Milowsky |  |  | David Ollila |  |  | Michael Winstead |
|  | Stergios Moschos |  |  | Travis Schrank |  |  |  |
|  | Hyman Muss |  |  | Julia Selfridge |  |  | **Gynecologic Oncologists** |
|  | Kirsten Nyrop |  |  | Philip Spanheimer |  |  | Victoria Bae-Jump |
|  | Matthew Painschab |  |  | Karyn Stitzenberg |  |  | John Boggess |
|  | Shetal Patel |  |  | Blake Sullivan |  |  | Wendy Brewster |
|  | Chad Pecot |  |  | Wendell Yarbrough |  |  | Leslie Clark |
|  | Emily Ray |  |  | Jen Jen Yeh |  |  | Olivia Lara |
|  | Katherine Reeder-Hayes |  |  |  |  |  | John Soper |
|  | Brandi Reeves |  |  | **Radiation Oncologists** |  |  | Katherine Tucker |
|  | Daniel Richardson |  |  | Dana Casey |  |  | Linda Van Le |
|  | Tracy Rose |  |  | Scott Chen |  |  |  |
|  | Samuel Rubinstein |  |  | Shekinah Elmore |  |  | **Co-Investigators Not Listed Above** |
|  | Hanna Sanoff |  |  | Gaorav Gupta |  |  |  |
|  | Jonathan Serody |  |  | Ellen Jones |  |  |  |
|  | Siddharth Sheth  |  |  | Lawrence Marks |  |  |  |
|  | Ashwin Somasundaram |  |  | Kevin Pearlstein |  |  |  |
|  | Jonathan Sorah |  |  | Michael Repka |  |  |  |
|  | Jacob Stein |  |  | Colette Shen |  |  |  |
|  | Astha Thakkar |  |  | Shivani Sud |  |  |  |
|  | Sascha Tuchman |  |  | Ashley Weiner |  |  |  |
|  | Hank van Deventer |  |  | Ari Wijetunga |  |  |  |
|  | Neeta Venepalli |  |  | Ted Yanagihara |  |  |  |

### Competing Trials/Prioritization

Please check one:

1. [ ]  ≥1 competing trials currently open or in the pipeline over the next 6 months. If so, please list trials and
 provide strategy for prioritization below.
2. [ ]  No competing trials open or in the pipeline.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **POD Leader Sign-Off**

If PI is POD Leader, PI may sign off on own study. If there are multiple disease groups to be recruited (e.g., Breast, Lung, etc.), please obtain sign-off from each DGL.

**By signing this form, I am indicating that I am aware of and approve this research study recruiting from the patient population for which I oversee. Any trials which may compete for this patient population are indicated above.**

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **POD Group Leader Signature** |  | **Date** |
|  |  |  |
| **POD Group Leader Printed Name** |  |  |

**Please note:** If a study includes both adult and pediatric patients, study sign-off will come from the group in which the study will be run. Please confirm an email notification about the study was sent to the respective oncologists in the other age group.

Primary Group: \_\_\_\_\_\_\_\_\_\_ Pediatric Oncology \_\_\_\_\_\_\_\_\_\_ Adult Oncology

Name(s) of persons notified: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date notification sent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_