PRC Cover Sheet for CTO Trials- Initial Submission

### Required Documents for Submission

1. PRC New Study Cover Sheet pulled from Oncore
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. Data and Safety Monitoring Plan and/ or Charter. Please specify page number if in protocol.
5. IND/ IDE Exemption Letter (when applicable).
6. [Biostatistician Sign-Off](https://www.unclineberger.org/protocolreview/new-studies/biostat-signoff) (for studies in which UNC Lineberger is the sponsor).
7. Questionnaires /Surveys/Instruments (when applicable).
8. Recruitment Material (when applicable).
9. 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.

### General Questions:

* If this study encompasses more than one phase (e.g., Phase I/II, Phase Ib/II, etc.); please indicate in which phases UNC will be participating: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Are there any Institutional COIs associated with this study? (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* If this is a treatment trial, does the team anticipate any difficulty in reaching at least 20 % accrual of underrepresented racial/ethnic groups. (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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### 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.

### POD Leader Sign-Off

If PI is POD Leader, PI may sign off on own study.

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

**List of Investigators:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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 |  |  |