PRC Amendment Cover Sheet for Non-CTO Managed Trials

### Items Required for Amendment Submission:

* PRC Amendment Cover Sheet.
* Clean version of Protocol.
* Track changes version of Protocol. (Please request from Sponsor.)
* Summary of Changes, if a separate document. (Please request from Sponsor.)
* If this is a UNC Lineberger Investigator Initiated Trial and the statistical section has been revised, please provide a Statistician Sign-off. (For questions about whether or not a Statistician Sign-off is required, please contact the UNC Lineberger Biostatistics Core at lccc\_bios@med.unc.edu.)
1. **Protocol**
2. Protocol Number:
3. Title:
4. IRB Number:
5. **Accrual Information**

|  |  |
| --- | --- |
| 1. What is the current total overall accrual goal for UNC?
 |  |
| 1. Will this number change with this Amendment?
 | [ ] Yes [ ]  No  |
| 1. If yes, what will be the new number? (Please note: If this is a UNC Lineberger IIT, and the new goal is increased or decreased ≥10 percent of the original goal, a justification will need to be provided. [See Question #5,](#_Please_note:_If) below.)
 |  |
| 1. What is the current annual accrual goal for UNC?
 |  |
| 1. Will this number change with this Amendment?
 | [ ] Yes [ ]  No  |
| 1. If yes, what will be the new number?
 |  |
| 1. How many total months overall is the study currently expected to be open to accrual?
 |  |
| 1. Will this number change with this Amendment?
 | [ ] Yes [ ]  No  |
| 1. If yes, what will be the new number?
 |  |
| 1. Is this study currently open to accrual?
 | [ ] Yes [ ]  No  |
| 1. If yes, what date did it open to accrual?
 |  |
| 1. How many total subjects have accrued to this study at UNC?
 |  |

1. **Proposed Amendment**

Please provide a short, detailed synopsis of the proposed amendment (e.g., addition of new arm, change to primary objective, addition of new disease group, etc.):

1. **Rationale for Amendment**

Please provide a short, detailed rationale for the proposed amendment:

1. **Justification for Change in Accrual for UNC Lineberger IITs Only**

If this is a UNC Lineberger IIT and the total expected accrual goal has increased or decreased ≥10 percent of the original goal, please provide a justification for the increase or decrease (i.e., an explanation on why changing the accrual goal of the study will still result in scientifically meaningful research).

1. **IND/IDE Process for UNC Lineberger IITs Only**
2. If this is a UNC Lineberger IIT, does the amendment affect any related Investigational New Drug (IND) or Investigational Device (IDE) associated with the study? If so, please provide a short, detailed explanation of the change:
3. If an Investigational New Drug is proposed to be used with this Amendment that was not previously associated with the trial, please provide the Investigator Brochure for that drug, as well as either an IND Exemption Letter or a completed IND Exemption Checklist.
4. If an Investigational Device is proposed to be used with this Amendment that was not previously associated with the trial, please provide a completed Investigational Device Worksheet to be filed with the UNC IRB application.
5. **Integrated/Integral Biomarkers for UNC Lineberger IITs Only**

If this is a UNC Lineberger IIT, does the amendment include any changes to collection and testing of integrated or integral biomarkers?

[ ] Yes [ ]  No

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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. **New Patient Population**

Does this amendment add a new disease group to the study? If so, please provide written notification (e.g., email) from the POD leader for the new disease group that indicates they are aware of the trial and have the resources available to accrue their patients to the study. If no written notification is available, please indicate why not.

1. **Competing Trials**

Please list any competing trials; if none, please insert None or N/A:

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

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