PRC Cover Sheet for CTO Trials – Amendment Submission

### Items Required for Amendment Submission:

* PRC Amendment Cover Sheet.
* LCCC PRC Amendment Coversheet Data report pulled from Oncore.
* 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 (IIT) and the statistical section has been revised, please provide a Statistician Sign-off. (If any questions, please contact the UNC Lineberger Biostatistics Core at lccc\_bios@med.unc.edu.)
1. **Accrual Information**

|  |  |
| --- | --- |
| 1. Will the current total overall accrual goal 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. Will the current annual accrual goal for UNC change with this Amendment?
 | [ ] Yes [ ]  No  |
| 1. If yes, what will be the new number?
 |  |
| 1. Will the total number of months overall that the study is currently expected to be open to accrual change with this Amendment?
 | [ ] Yes [ ]  No  |
| 1. If yes, what will be the new number?
 |  |

1. **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. **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. **Competing Trials**

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

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**Questions 6-8 are for UNC Lineberger IITs Only**

1. **Justification for Change in Accrual**

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**
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**

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

**List of Investigators (Reference Guide for PRC Reviewers)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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 |  |  |  | Ian Davis |
| James Coghill |  | **Surgical Oncologists** |  | Catherine Habashy |
| Frances Collichio |  | Jeffrey Blumberg |  | John Hipps |
| Claire Dees |  | Jeremiah Deneve |  | George Hucks |
| Christopher Dittus |  | Matt Ewend |  | Kimberly Kasow |
| Shakira Grant |  | Kristalyn Gallagher |  | David Kram |
| Natalie Grover |  | Elizabeth Gleeson |  | Gerardo Quezada |
| Katarzyna Jamieson |  | Trevor Hackman |  | Barbara Savoldo |
| Caron Jia |  | Hong Jin Kim |  | Andrew Smitherman |
| William Kim |  | Lawrence Kim |  | Patrick Thompson |
| Carrie Lee |  | Michael LeCompte |  | Kate Westmoreland |
| Eben Lichtman |  | Catherine Lumley |  | Michael Winstead |
| Brian Miller |  | Michael Meyers |  |  |
| Matthew Milowsky |  | David Ollila |  | **Gynecologic Oncologists** |
| Stergios Moschos |  | Travis Schrank |  | Victoria Bae-Jump |
| Hyman Muss |  | Julia Selfridge |  | John Boggess |
| Kirsten Nyrop |  | Philip Spanheimer |  | Leslie Clark |
| Matthew Painschab |  | Karyn Stitzenberg |  | Olivia Lara |
| Shetal Patel |  | Blake Sullivan |  | John Soper |
| Chad Pecot |  | Wendell Yarbrough |  | Katherine Tucker |
| Emily Ray |  | Jen Jen Yeh |  | Linda Van Le |
| Katherine Reeder-Hayes |  |  |  |  |
| Brandi Reeves |  | **Radiation Oncologists** |  |  |
| Daniel Richardson |  | Dana Casey |  |  |
| Tracy Rose |  | Scott Chen |  |  |
| Samuel Rubinstein |  | Shekinah Elmore |  |  |
| 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 |  |  |