PRC Cover Sheet for CTO Trials – Renewal Submission

*PRC annual renewal submissions for all oncology-related studies are due at the same time as the UNC IRB annual renewal submissions.*

### Items Required for Renewal Submission (see separate Tip Sheet for more information):

* PRC Renewal Cover Sheet
* PRC Renewal Cover Sheet Data Report from Oncore.
* Most recent IRB Renewal Applications from all applicable IRBs (UNC, CIRB, etc.).
* Current Protocol. If the protocol has been amended since the last time it received an annual review by the PRC, also include a track changes version and/or a Summary of Changes.
* IRB Approval Letters from all applicable IRBS (UNC, CIRB, etc.) for each modification approved since time of last renewal review.
* All SAEs and/or PRIs since time of last renewal review. Documents to be provided for PRIs include the actual report (and any modifications) filed with the applicable IRB (UNC, CIRB, etc.), as well as all responsive IRB letters.
* DSMC or DSMB Report Letters since time of last renewal review, as well as all responsive documents, including CAPAs, addressing any issues outlined in the DSMC or DSMB Report Letters.
* Audit Report Letters and/or Monitoring Letters since time of last renewal review, as well as all responsive documents, including CAPAs, addressing any issues outlined in the Audit Report Letters or Monitoring Letters.
1. **Current Status of Trial**

Please provide a short synopsis of the current status of the trial (e.g., will close to accrual within a few months; currently only has two patients on active follow-up; accruing steadily and on target; study is currently in Phase I, with plans to open Phase II next year; etc.). **If the study has been on hold for any length of time during the past year, please indicate the reason for the suspension and the number of months that the study was on hold.**

1. **Competing Trials**

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

1. **Low Accrual Information**

NCI Core Grant guidelines mandate closure of poorly accruing studies. As such, a rationale for low accrual must be included with the PRC renewal submission if:

* Accrual over the past cycle has been less than 40% of the original stated annual accrual goal.

Please ensure the following points are addressed in your submission:

1. Please provide a rationale for low accrual, including what challenges have led to accrual being lower than expected for this trial. This may include delays in trial activation, suspension for interim analysis, population not as estimated, etc.
2. Please provide an action plan to indicate what strategies will be implemented to ensure stated accrual goals will be achieved (e.g., new methods of recruitment, changes to the study which may facilitate enrollment, opening of study at multicenter sites (with information on when these sites opened to accrual), reduction of annual accrual goals to be in keeping with current accrual trends, etc.).
3. 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).
4. **Protocol Amendments**

If the protocol was amended since last PRC renewal review, please provide a short, detailed synopsis of the changes:

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

Has the protocol been modified since last PRC review to now 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**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 |  |  |  | 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 |  |  |