

TIP SHEET FOR UNC LINEBERGER PRC ANNUAL RENEWAL SUBMISSIONS

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

Renewal submissions are due to the PRC for the following studies:

- ✓ Studies that are Open to Accrual.
- ✓ Pharma, IIT or Other Institution studies that are Closed to Accrual but still have subjects on treatment or active follow-up (research-related intervention/interaction continues with any subjects). Note that Cooperative Group studies are not required to submit PRC renewal submissions once they have Closed to Accrual, whether or not there are still subjects on treatment.
- ✓ Studies that are not yet Open to Accrual but more than six months have passed since the PRC Initial review.
- ✓ Studies that are currently Suspended or On Hold, no matter the reason.
- ✓ Cooperative Group studies (e.g., Alliance, NRG Oncology, etc.) that have not met 40% of their current annual accrual goal (as reflected in OnCore) during the past year (since the last UNC IRB renewal).

Items Required for Renewal Submission:

- PRC Renewal Cover Sheet.
 - Please answer all questions on the cover sheet, even if with None or N/A.
- Most recent IRB Renewal Applications from all applicable IRBs (UNC, CIRB, etc.).
 - PRC annual submissions are due at the same time as the UNC IRB annual submission. Although the IRB renewal applications are required for the PRC submission, it is not required to wait for the IRB renewal approval letters before submitting to the PRC.
- 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.
 - Both track changes versions and SOCs are preferred, if available from the Sponsor.
 - Remember to update question #5 on the cover sheet if the protocol has been amended.
- IRB Approval Letters from all applicable IRBs (UNC, CIRB, etc.) for each modification approved since time of last renewal review.
 - This applies to all modifications, even personnel changes.
- All 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.
 - Attachments, such as safety reports, are not required. Only the actual PRI reports and 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.
 - For UNC Lineberger IITs, DSMC review dates are reflected in OnCore. For all others, please double-check all files, including Investigator Site files, for these documents, and please reach out to the Sponsor if needed.
- 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.
 - Correspondence regarding upcoming visits is not required; only reports sent after the visits, as well as correspondence confirming resolution of any issues raised during monitor visits. If monitor visits are tracked in OnCore, ensure reports for each visit during the applicable time frame are provided.

1. Protocol

- Please answer all questions. If it is not clear if the study treats a rare disease population, please consult with the PI.

2. Accrual Information

- The requested information is for UNC accruals only. If a study is a multicenter trial, only UNC information should be provided.
- This information is found in OnCore under the Main/Details tab of PC Console. Any changes made since last PRC renewal review to Total Accrual goal, Annual Accrual goal or Duration should be reflected on the cover sheet.
- Note that Total Goal = Annual Goal X Duration. For example, 10 subjects (Total Goal) = 5 subjects (Annual Goal) X 24 months (Duration). Therefore, if a change has been made to one factor, changes may need to be made to the remaining factors.
- While the UNC IRB tracks subjects who have *consented* to the study, the PRC tracks UNC subjects who have *accrued* to the study. This number should be reflected in OnCore.
- For Cooperative Group studies, if the study has reached 40% of its current Annual Goal during the past year (since the last UNC IRB renewal), a PRC renewal submission is not due. For example, if the IRB expiration date is March 2023, the Annual Goal is 5 subjects, and the study has accrued 2 subjects (40%) since March 2022, a PRC renewal submission is not due.

3. Current Status of Trial

- If a study is currently Suspended or On Hold, please include the reason why as well as an estimated time frame for when the study will reopen. If the study has not yet opened, please include an estimated time frame for when it will open.

4. Low Accrual Information

- Low accrual information is required for all studies that do not reach 40% of their current Annual Accrual goal.

5. Protocol Amendments

- Please include a short summary of any changes. If a SOC from the sponsor is several pages long, do not copy and paste into the cover sheet.
- If a protocol has been amended more than once since last PRC review, include a short summary for each amendment.

6. Demographics of Subject Population

- This question must be answered for interventional treatment trials. A demographics report can be created for this information (Reports/Demographics by Protocol).

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

- For UNC Lineberger IITs only.

8. Competing Trials

- This question must be answered. If it is not known whether there are any competing trials, please consult with the PI.

9. Staff

- All Co-Investigators listed with the UNC IRB should also be listed in OnCore and also on the cover sheet. The list of Co-Investigators should match in all three locations. Any Co-Is who are not already listed on the cover sheet should be added under the column, "Co-Investigators Not Listed Above."