

Protocol Review Committee (PRC)

IRB Presentation
September 2018



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What is the PRC?

- A multidisciplinary standing Committee of LCCC and the UNC Clinical Cancer Program (see PRC website: <http://unclineberger.org/protocolreview>)
- Joint entity of LCCC, UNC Hospitals and the UNC School of Medicine
- Thirty-three primary members comprised of rotating group of faculty physicians from hematology/oncology, UNC biostatistics faculty and specialized ad hoc members

- PRC Chair:
Autumn McRee, MD
- PRC Coordinator:
Stacy Maxwell



What are the Primary Functions of the PRC?

- Provide peer review of local and national research protocols involving cancer prior to IRB submission
- Ensure the scientific quality and patient safety of proposed studies
- Monitor study progress/accrual and may recommend closure of under-performing trials (via annual renewal review)

What Does the PRC Review?

- Any study that recruits from the UNC Health Care clinical settings for cancer patients or that has a focus on cancer, including:
 - Treatment studies
 - Non-treatment studies
 - Correlative science studies
 - Studies in the community that are focused on cancer and involve an intervention
 - Observational studies that recruit UNC cancer patients

What Does the PRC Review (cont.)?

- Studies that are managed by the Clinical Protocol Office (CPO)
- Studies that are NOT managed by the CPO (Non-CPO)
- Investigator Initiated Trials (IITs), whether UNC initiated the trial or is just a participating site
- Pharmaceutical sponsored trials
- Cooperative group/other externally peer reviewed studies (e.g., NCI)

What Does Not Require PRC Review?

- Studies that do not involve direct interaction with participants, such as:
 - Retrospective reviews of medical records
 - Studies not related to cancer
- When in doubt, contact PRC Coordinator

Documents Required for PRC Review

- Protocol (use of an LCCC template required for all IITs)
- PRC Submission Cover Sheet
- Investigator's Brochure
- RAFT approval (for CPO-managed studies only)
- Biostatistician signoff (for UNC IITs)
- See PRC website for full description of requirements

LCCC Protocol Templates

- Six templates available:
 - Cellular therapy
 - Chemotherapy
 - Radiation treatment
 - Health services research
 - Correlative studies
 - Imaging studies
- Protocol Development (919.843.7130) provides any assistance needed with study and protocol development

PRC Submission Cover Sheet

- Requires Disease Group (POD) sign-off
- For CPO Studies:
 - Provides evidence study discussed in POD
 - Offers avenue to address potentially competing studies and prioritization
- For Non-CPO Studies:
 - Ensures POD is aware and supportive of any study that may interact with their patient population(s)

RAFT Approval

- Indicates approval by RAFT Committee to move forward
- Required for any CPO study to continue on to PRC (and other reviews)
- RAFT can (and does) disapprove studies

Statistical Requirements

- UNC Biostatistician signoff
- Required for any UNC IIT
- Ensures statistical input into trial design
- Ensures pilot and feasibility trials include a clear measure of success and appropriate sample size calculations
- UNC LCCC Biostatistics Core available to help if needed (<http://unclineberger.org/research/core-facilities/biostats/overview>)

PRC Meetings

- Full reviews (two clinicians and one statistician)
- Meetings take place on Wed ~every 2 weeks throughout the year
- Coordinated with IRB Committees B & D – 12 days before
- Studies put on agenda in order of submission
- Five initial reviews and ten renewal reviews per meeting

PRC Meetings (cont.)

- PRC classifies new studies by complexity and risk which then determines frequency of DSMC review
- All studies submitted to PRC first, then submitted to IRB with PRC approval letter
- Once PRC notified of IRB submission, study approved in IRBIS
- In 2016 – 330 reviews; in 2017 – 411 reviews

Does PRC Review Amendments?

- Yes, if the amendment involves one or more of the following:
 - Adding a new drug or new treatment modality (e.g., radiation, surgery, etc.)
 - Changing the primary objective
 - Requiring change in statistical plan (LCCC IITs only)

Other Types of PRC Review

- Annual Renewals
 - Main focus is on study performance (accrual), though also focus on any study updates and safety/monitoring information
 - Approval for one year
 - Objective bar of 40% of stated accrual = low accrual

Other Types of PRC Review

- Six-Month Re-Review
 - Occur if, at time of renewal review, the study is underperforming
 - PRC can close studies if they don't meet their mark
- Specific information on what is required for PRC reviews (all types) can be found on our website, or by contacting the PRC Coordinator

UNC Lineberger
Protocol Review Committee
<http://unclineberger.org/protocolreview>

Feel free to contact
me with any questions:

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Thank you