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UCCC Protocol Review and Monitoring Committee (PRMC) Charter

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Document History				
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May 27, 2020	June 23, 2020	Charter updates to clarify requirements for PRMC review of Major Amendments. Edits throughout to reflect change in cancer center name from UCCI to UCCC.	Christine Vollmer- UCCC Regulatory Manager	Approved by UCCC PRMC Chair June 23, 2020

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I. Purpose of the UCCC PRMC

The purpose of the University of Cincinnati Cancer Center (UCCC) Protocol Review and Monitoring Committee (PRMC) is to ensure that all cancer related clinical research studies conducted through the UCCC have scientific merit, meet the scientific priorities of the UCCC, are logistically feasible, and demonstrate reasonable progress once opened. Special considerations may apply to trials of rare diseases, or unique therapies, which often do not accrue rapidly.

The PRMC serves as a mechanism for assuring adequate internal oversight of the scientific aspects of all the cancer clinical trials at the University of Cincinnati Medical Center and Cincinnati Children's Hospital Medical Center.

II. Scope of the UCCC PRMC

The UCCC PRMC is not intended to duplicate, or overlap with, the responsibilities of an IRB. Auditing for quality control or safety reasons is not a function of the PRMC, but rather is a function of the UCCC Data Safety Monitoring Board (DSMB). UCCC DSMB committee functions and PRMC committee functions are separate and distinct from one another and should not overlap. The focus of the PRMC is on scientific merit, priorities, feasibility, and progress of UCCC clinical research protocols.

III. Definitions

The following are definitions meant to be used in the interpretation of this Charter. If not expressly used within this Charter, it is understood these will be used to guide committee actions and internal UCCC PRMC processes.

A. **Study Source** is defined as one of the following:

1. *National*: NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks.
2. *Industry*: A pharmaceutical or device company controls the design and implementation of these clinical research studies.
3. *Externally Peer-Reviewed*: R01s, SPORES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or organizations on this list: [Organizations with Peer Review Funding Systems](#).
4. *Investigator-Initiated Trials (IITs)*: Those trials which are primarily designed and sponsored by an Investigator rather than by an industry

sponsor. It is acceptable for industry and other entities to provide support (e.g., drug, device, other funding), but the trial should clearly be the intellectual product of the investigator.

5. *Multi-Institutional Clinical Research Study*: Clinical Research studies that recruit participants from a geographically distinct Institution not affiliated with UCCC (e.g., other NCI-designated Cancer Centers or other research institutions).

B. Clinical Research Categories are defined as follows:

1. *Interventional*: Trial on which individuals are prospectively assigned based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.
2. *Observational*: Studies that focus on cancer patients and/or healthy populations and involve no prospective intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions, but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.
3. *Ancillary*: Studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported to NCI.
4. *Correlative*: Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported to NCI.

C. Primary Purpose must be assigned to Interventional or Non-Interventional (Observational or Ancillary/Correlative) Clinical Research Categories:

1. *Basic Science*: Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention.
2. *Device Feasibility*: Protocol designed to evaluate one or more interventions for the feasibility of the product or to test a prototype device and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial.

3. *Diagnostic*: Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition.
4. *Health Services Research*: Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.
5. *Prevention*: Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.
6. *Screening*: Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).
7. *Supportive Care*: Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant's health or function. In general, supportive care interventions are not intended to cure a disease.
8. *Treatment*: Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. (Note: This equates to therapeutic trials in previous versions of the NCI guidelines).
9. *Other*: Not in other categories.

IV. Procedures for Study Teams

Regardless of the type of PRMC review a study will undergo, all studies should utilize the PRMC procedures outlined below. Studies which do not provide all of the materials outlined in sub-parts A & B of this section will not be scheduled for consideration by the PRMC until all missing items are provided.

Study teams must provide the following materials outlined in 1-3 below (as applicable) to the UCCC PRMC Coordinator:

1. **UCCC PRMC Routing Sheet, Protocol & IB or Pharmacy Manual**
 - ✓ All studies **must** complete the *UCCC PRMC Routing Sheet*, which should be reviewed and signed-off on as accurate by the PI and respective Disease Specific Clinical Trials Leader or Center of Excellence Leader (or Department/Division Chair if the protocol does not fall under a disease specific group).
 - ✓ All studies **must** provide a finalized study protocol.
 - ✓ All **Phase 1 studies or studies involving a non-FDA approved drug** must provide an Investigator's Brochure (IB) or Pharmacy Manual.

2. **For Studies Undergoing UCCC IIT Committee Review** Any IIT which will utilize UCCC CTO staff (Regulatory/Monitoring/CRCs etc) in the conduct of the trial must provide written documentation from the UCCC IIT Committee noting the successful completion of IIT Committee review.

3. **Prioritization Plans for Competing Trials** Study teams must indicate on the *UCCC PRMC Routing Sheet* whether there are any studies, which are “competing trials,” meaning there is an overlap in eligibility criteria or patient populations or aims such that the proposed trial may reduce the ability of the other(s) to enroll.
 - a. *For Studies With Known Competing Trials*: Study teams **must** submit a prioritization plan, outlining what the team will do when confronted with a subject who may be eligible for more than one competing studies (e.g., which study the subject will be enrolled to and why). Failure to submit a plan may result in the tabling or disapproval of a study by the PRMC.

4. **Study Team Attendance at PRMC** A PI may attend the PRMC meeting at which their study will be reviewed in order to provide the committee with any clarifications or other information that may impact the committee’s decision (attendance is not required and may be done remotely). Due to conflicts of interest, the PI and any Sub-Investigators or other study team members (CRCs, Regulatory etc...) may not be present during the deliberations of the committee, including assigned reviewer overviews.

Due to reasons of confidentiality, PIs or Sub-Investigators or study team members (CRCs, Regulatory etc...) who are not PRMC Members may also not be present for the deliberations or reviewer overviews for other studies on the committee agenda (including those undergoing accrual review) for which they do not serve as PI or Sub-I or are on the study team.

5. **Timelines for Submission**

Timelines for submission are dependent on submission type, but generally:

- a. *Administrative & Fast Track Reviews* for Initial and Major Amendments are accepted on rolling basis and will be assigned for review upon receipt of all required materials by the PRMC Coordinator.

- b. *Full Committee Review*: all required materials must be received by the PRMC Coordinator at least 10 business days (~2 weeks) in advance of the

PRMC meeting to ensure adequate time for review (exceptions may be made at the discretion of the PRMC Coordinator or PRMC Chair).

V. PRMC Review Types & Procedures for New Studies

There are three tiers of review that New or Ongoing studies submitted to the UCCC PRMC may undergo: **Administrative, Fast-Track and Full Review.**

Note: if a study is determined to be “Not Rare” (see *Section VII PRMC Review of Ongoing studies*) and total accrual is projected to be 3 or fewer subjects or annual accrual is projected to be 3 or fewer subjects; then Full Review by the PRMC will occur by default (with the exception of Expanded Access or Emergency Use studies).

A. Types of Studies Not Requiring Review by the PRMC: Studies which are comprised **solely** of the following categories are not subject to PRMC review.

1. Retrospective chart reviews (medical records reviews).
2. Studies involving non-identifiable data/tissue which do not require patient consent to perform.
3. In vitro studies that utilize human tissues that cannot be linked to a living individual.
4. Studies only involving the administration of surveys or questionnaires requiring consent or with a waiver of consent.
5. Studies which are exempt from IRB review.

B. Type of Studies Eligible for Administrative Review:

1. NCI-approved National Cooperative Group studies that have undergone central review.
2. Other NCI-peer reviewed protocols (e.g., clinical research studies approved by NCI’s Cancer Therapy Evaluation Program, Division of Cancer Prevention, or the Cancer Control Protocol Review Committee).
3. Studies which are externally peer-reviewed and are supported by the various NIH mechanisms (e.g., R01s, SP0RES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or organizations on the NCI’s Organizations with Peer Review Funding List <https://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C.pdf>).

4. Multi-center studies already approved by the NCI-approved PRMS of the lead site **if** the UCCC PRMC Coordinator is in receipt of documentation demonstrating the PRMS approval belongs to an NCI-designated Cancer Center **and** documentation of approval of the study by the reviewing PRMS.

C. Process for Administrative Review

The PRMC Coordinator (or other delegated member of the UCCC office) reviews the *UCCC PRMC Routing Sheet* and submitted materials to acknowledge research team prioritization plans for competing studies and resource utilization through appropriate study team routing form sign-off.

Administrative Reviews will be completed by the PRMC Coordinator and a Determination Letter issued to the study team by the PRMC Coordinator within seven (7) business days of receipt of all required study materials. Studies approved by Administrative Review will be listed on the agenda of Full PRMC meetings to allow for acknowledgement by the Full Committee.

D. Type of Studies Eligible for Fast-Track Review

1. Phase 1 Research Trials that are NOT Investigator Initiated Trials (IITs).
2. Expanded Access (Compassionate Use) Protocols (*as defined in 21 CFR 312 Subpart I*).
3. Emergency Use Protocols (*as defined in 21 CFR 56.102(d)*):
 - i. The PRMC must be notified within five (5) business days (or sooner) after the emergency use/consent occurs. Whenever possible, the treating physician will consult with the PRMC Chair, prior to use.
4. Studies with contractually required reduced approval timelines (e.g., Novartis Signature, IQVIA Precision Enrollment (IQVIA PE), or Optimal Research).

E. Process for Fast-Track Review:

Upon receipt of all required materials, studies are assigned by the PRMC Coordinator to **one committee member who serves as the primary reviewer** for scientific review, **and a biostatistician** for a statistical review. Phase 1 non-IITs will always have a **Pharmacist** assigned in addition to the standard reviewers. **The PRMC Chair** will perform the review for Compassionate Use or Emergency Use studies. All reviewers may always request any additional reviewers needed to ensure the scientific validity of the request (e.g., pharmacy, disease specialty focused member etc.).

Committee members should complete all Fast-Track reviews within a two week period (~10 working days) by reviewing and submitting their determinations electronically to the PRMC Coordinator. If after 10 business days the assigned reviewer has not performed their review, then the PRMC Chair may be assigned to complete the review. In the event the PRMC Chair is conflicted, the Chair will delegate this review to a non-conflicted member of the committee.

A decision letter will be issued by the PRMC Coordinator to the study team as soon as possible but no later than 2 business days of receipt of the Fast-Track decision. Studies approved by Fast-Track Review will be listed on the agenda of Full PRMC meetings to allow for acknowledgement by the Full Committee.

1. *Process for Contractually Required Fast-Track Reviews*

Protocols, or programs for which there are contractual obligations for significantly reduced IRB approval timelines (e.g., less than 1 month from contracting to study activation) **must** be reviewed by the PRMC. The **PRMC Chair** may perform the review and will request any additional reviewers needed to ensure the scientific validity of the request (e.g., stats, pharmacy, disease specialty focused member etc...).

Study teams should not delay submission to the UC IRB, but may complete the IRB and PRMC submission in tandem for such studies. The UCCC CTO has on file documentation from the UC IRB acknowledging this variance in process which study teams should provide with their IRB submission in lieu of PRMC approval. PRMC approval should be provided to the IRB as soon as practicable prior to study activation.

F. Types of New Studies Eligible for Full Review: Full PRMC Committee review is required for studies that meet all three of the following criteria:

1. Cancer-related study that involves recruitment of UCCC or CCHMC cancer patients or use of identifiable tissue/specimens; and
2. Study has a research intervention (e.g., subjects would not have the drug, device, radiation, imaging, surgical technique, extra biopsy/blood draw etc...as standard of care); and
3. Study for which full scientific review is not performed by an external NCI-approved review process.

G. Process for Full Review:

Upon receipt of all completed required submission materials, studies are assigned by the PRMC Coordinator to committee members to serve as a **primary reviewer** and a **secondary reviewer** for scientific review, to a **biostatistician** for a statistical review, and to a **pharmacy** reviewer and **budgetary** reviewer as needed.

The study will be reviewed by the Full PRMC Committee. After the Full Meeting, a determination letter will be issued by the PRMC Coordinator to the study team as soon as possible but typically no later than 5 business days after the meeting date.

VI. PRMC Review Decision Types

Upon review, studies submitted to the PRMC for Initial Review, Major Amendment Review or Accrual Review may receive one of the following determinations.

- A. **Approved**: The protocol is acceptable as reviewed and may be submitted to the IRB, or accrual is acceptable.
- B. **Approved with Administrative Contingencies**:
The PRMC has identified administrative items of concern which must be addressed in writing to the PRMC Coordinator.
 - No additional review of the study team response by the PRMC is required prior to IRB submission but it may be requested at the discretion of the PRMC Coordinator or Chair.

Examples of Administrative Contingencies include: Unknown or unconfirmed collaboration of personnel or financial support. Or other items which do not materially impact scientific merit or feasibility, such as grammatical errors or minor clarifications.

- C. **Approval Deferred - Minor Contingencies**:
The protocol requires minor revision(s) or there were significant clarifications noted in the review that must be addressed prior to proceeding with an IRB submission due to the impact on study feasibility or scientific merit.
 - All such concerns **must** be addressed by a written response by the PI. This written response and amended documents with changes tracked (if applicable) will be reviewed in an expedited manner (Fast-Track) before approval may be issued (by the original reviewer(s) assigned whenever possible).

- If **no PI response is received** by the PRMC Coordinator/PRMC within 3 months or 3 Full PRMC meetings (whichever is longer) from the original review date, the study will be automatically removed from the PRMC agenda and must be re-submitted by the study team for consideration.
- If **all contingencies are not resolved** within 6 months or 6 Full PRMC meetings from the original review date, the study will be automatically removed from the PRMC agenda and must be re-submitted by the study team for consideration.

Examples of Minor Contingencies include: inconsistencies/errors within the protocol, missing forms referenced in the protocol which impact study procedures/scientific merit/feasibility, accrual barrier questions, missing or unclear AE section/table, competing protocol issues/concerns or an unclear prioritization plan (if applicable).

D. **Approval Deferred - Major Contingencies:**

The protocol requires major revisions, or there are major concerns regarding the application materials that must be addressed prior to proceeding with an IRB submission due the impacts on study feasibility or scientific merit.

- All concerns **must** be addressed in writing by the PI and the revised application with changes tracked must be formally reviewed by the Full PRMC before approval may be issued (with the original reviewer(s) will be assigned, whenever possible).
- If **no PI response is received** by the PRMC Coordinator/PRMC within 3 months or 3 Full PRMC meetings (whichever is longer) from the original review date, the study will be automatically removed from the PRMC agenda and must be re-submitted by the study team for consideration.
- If **all contingencies are not resolved** within 6 months or 6 Full PRMC meetings from the original review date, the study will be automatically removed from the PRMC agenda and must be re-submitted by the study team for consideration.

Examples of Major Concerns include: questions regarding the adequacy of the statistical plan, questions relating to safety data or risk assessment, eligibility

criteria, stratification rationale or the treatment plan. Lack of a prioritization plan (if applicable). Lack of/unclear Data and Safety Monitoring Plan (if applicable)

- E. **Tabled**: A study may be tabled without a formal decision being issued, if:
1. The Committee is unable to reach a decision due to missing/incomplete PRMC reviews and/or,
 2. The PI or their designee is not in attendance or able to be contacted during the meeting, and the committee does not wish to issue a determination prior to discussions with the PI; and/or
 3. Lack of PRMC quorum.
- F. **Disapproved**: The committee may disapprove a study due to lack of scientific merit, feasibility, inadequate justification/prioritization with competing trials, and/or inadequate resources (lack of staffing, equipment, patient population, funding etc..) to complete the trial. PI's may appeal the PRMC's determination in writing within 30 business days to the PRMC.

G. **Re-Review**:

If it is found *after PRMC Initial Approval has been issued* upon any subsequent PRMC review that the study team has: failed to address the PRMC's Contingencies (including failure to provide written responses to the PRMC Coordinator) and/or has performed the study in a manner inconsistent with the originally approved protocol such that **scientific merit** and/or **feasibility** may be materially impacted this may result in the PRMC's *de novo* consideration of the scientific merits and/or feasibility of the study by the Full Committee.

Re-Review may result in an alteration or revocation of the PRMC's initial approval, up to and including permanent study closure to accrual. PI's may appeal any decision resulting from the PRMC's Re-Review determination in writing within 30 calendar days to the PRMC.

- H. **Study Closure (Temporary or Permanent)**: The PRMC may close a study to accrual permanently or temporarily if the study team fails to meet the accrual goals set forth within this Charter (*see Section VII Ongoing Studies*) or if it is found that the study team has not adhered to the requirements/criteria under which a study received initial or ongoing PRMC approval. PI's may appeal the PRMC's determination in writing within 30 business days to the PRMC.

VII. PRMC Review for Ongoing Studies

A. Changes to Approved Studies - Major Amendments

UCCC PRMC review of changes to PRMC-approved protocols is only required when the change qualifies as a Major Amendment, or upon IRB request. A “Major Amendment” is one that results in a change to the science of the study and involves a change to at least one of the following:

1. Study objectives
2. Eligibility criteria
3. Treatment plan (e.g., dosing changes/arm additions)
4. Statistical/Analysis plan

The UCCC CTO Regulatory department in collaboration with PRMC chair will determine if the amendment requires review by the PRMC.

B. Process for Major Amendment Review

Study teams must submit a Major Amendment Request Form along with any required documents (IB, Summary of Changes and/or Tracked Changes Protocol etc...) to the PRMC Coordinator who upon receipt of all required materials, will route the request to receive the appropriate type of review as indicated below:

1. Studies initially approved using Administrative Review will have any Major Amendments reviewed using Administrative Review.
2. If a protocol was initially approved using Administrative or Fast-Track Review and the revised protocol no longer meets the criteria for the original review category, the review type for which the study now qualifies will be used.
3. All other Major Amendments will be reviewed by Fast-Track Review by a single Primary Reviewer with Statistical review by a Biostatistician if the major amendment includes changes to the statistical/analysis plan and Pharmacy review for changes to the Treatment Plan. Assigned reviewers or the PRMC Coordinator may request a Full Committee review at their discretion.

Review completion and issuance of decisions will be processed according to the time-frames outlined specific to each review type within this Charter. Major Amendments approved by Administrative and Fast-Track Review will be listed on the agenda for Full PRMC meetings to allow for acknowledgement by the Full Committee.

C. Accrual Reviews

The UCCC PRMC has the authority to close a study to accrual due to lack of reasonable scientific progress which may be demonstrated by not reaching accrual goals.

1. Study Eligibility for Accrual Review

Only **interventional** studies (regardless of PRMC review type) are eligible for Accrual Review, however the PRMC has the discretion to require Accrual Review for any study under its purview. Studies which have permanently closed to accrual are no longer eligible for Accrual Review.

2. Definition of “Rare”

A disease/tumor is considered “Rare” if:

- The **incidence is <6/100,000/year** (the RARECARE tumor list <http://www.rarecare.eu/rarecancers/rarecancers.asp> may be used as a reference but rates occurring in the United States will be given more weight), **or**
- If the disease is a molecular or biologically defined subset such that the **annual incidence is < 20,000** in the United States.

3. Timing of Accrual Reviews & Criteria for Closure

Studies without continuous recruitment from activation (e.g., temporary suspensions) will have their Accrual Review date extended by the length of non-enrollment to allow for a full accrual period. Study teams outside of the UCCC CTO will be asked to provide accrual data to the PRMC Coordinator for use in determining if accrual goals are met. Repository

Studies with low accrual requiring a PI Action Plan, will undergo Accrual Review 6 months (or sooner, at the determination of the PRMC) from the date the PRMC approves the PI Action Plan to allow the PRMC to review the effectiveness of the provided PI Action Plan, as well as the study’s accrual to date, to determine if the study will be considered for closure.

Process for Not-Rare Diseases/Tumors

- If a study has less than 50% of the projected annual accrual goal after 12 months since activation, a low-accrual notice letter is sent to the study team and a PI Action Plan is required.
- If a study in the last 12 month review period has less than 50% of the projected annual accrual goal after 2 years of active enrollment, the study may be closed.

Process for Rare Diseases/Tumors

- If a study has zero accrual after 18 months, a low-accrual notice letter is sent to the study team and a PI Action Plan is required.
- If a study has zero accrual after 3 years (4 years for Pediatric Oncology studies) it may be closed. However, if there are no other similar Pediatric Oncology studies open to accrual which would provide a non-standard of care treatment option for the rare disease/tumor being studied, then the study may remain open an additional year (5 years). If such a Pediatric Oncology study has zero accrual after 5 years, it will be closed.

Process for Closure if No PI Action Plan is Received

- If **no PI action plan is received** by the PRMC Coordinator/PRMC within **30 days or 1 Full PRMC meeting** (whichever is longer) from the original accrual review date, a second notice will be sent to the PI and study team.
- If **no PI action plan is received** by the PRMC Coordinator/PRMC within 60 days or 2 Full PRMC meetings (whichever is longer) the study will be automatically **Temporarily Closed to Accrual** by the PRMC and a third notice will be sent to the PI, the study team, the Disease Specific Clinical Trials Leader (or Dept./Division Chair for those studies that do not have a clinical trial leader) and/or Medical Director.
- If **no PI action plan is received** by the PRMC Coordinator/PRMC within 90 days or 3 Full PRMC meetings (whichever is longer) the study will be automatically **Permanently Closed to Accrual** by the PRMC.

VIII. Committee Management & Quorum

A. Quorum

Quorum is no less than **8** full committee members and must include either the chair, or chair designee if the chair is absent and at least one statistician. Members may be present in person, or remotely attend (phone, Skype etc.).

B. Membership

Committee members are nominated by the PRMC Chair who also makes the final committee appointments. Membership duration is flexible to maintain required

depth and breadth of expertise related to the spectrum of clinical research conducted at UCCC.

Members will provide sign/dated CVs, Conflict of Interest statements, and signed acknowledgement of the following attendance expectation annually.

Any member **who attends fewer than 8 meetings within a 1-year period** absent extenuating circumstances (e.g., medical leave) may have their membership revoked. Members who will be unable to attend the meeting, but who are able to **provide their completed review in advance of** the meeting will be considered to be “non-attending but present” when membership metrics are compiled.

Members who fail to meet the above attendance criteria will be provided with a written reminder via email (Chair cc'd) after two (2) absences or failures to provide reviews in advance of the meeting. After three (3) absences or failures to provide reviews in advance of the meeting, a second written notice will be provided via email and the PRMC Chair will meet with the member. After four instances, the member will be notified that their membership will be revoked absent evidence of extenuating circumstances and written Chair approval of continued membership.

C. **Responsibilities**

- a. **Primary Reviewer:** Committee member that is not a biostatistician that presents thorough synopsis, study design and review of protocol.
- b. **Secondary Reviewer:** Committee member that is not a biostatistician that summarizes synopsis, study design and review of protocol.
- c. **Statistical Reviewer:** Biostatistician that presents a thorough review of the statistical portion of the protocol.
- d. **Pharmacy Reviewer:** Pharmacist who will be assigned reviews ad hoc to provide specific feedback on dosing, con-meds, or other drug-specific information.
- e. **Budgetary Reviewer:** Person within the UCCC Clinical Trials Office who will provide feedback on whether there will be any impacts on the ability of a trial (e.g., IITs) to meet scientific goals due to funding concerns.
- f. **Committee Member Responsibilities:** Members are expected to attend all meetings in person or remotely. If they are not able to attend, they should ensure their alternate is able to attend. Members are expected to serve as Primary, Secondary, or Statistical Reviewers when assigned, and to engage in a robust discussion of each study under review.

- g. **Chair Responsibilities:** The Chair is expected to attend all meetings in person or remotely. Chair Designee(s) are expected to attend in the absence of the Chair.

D. **Meeting Schedule**

- a. The UCCC PRMC meets as a Full Committee on a monthly basis, but *ad hoc* Full Committee meetings may be conducted virtually, via email, or in-person as needed to ensure timely review or re-review of protocols occurs. The committee will strive to be flexible and accommodating of time-sensitive research deadlines.

IX. References

Cancer Center Support Grants (CCSGs) for NCI-designated Cancer Centers (P30)
<https://grants.nih.gov/grants/guide/pa-files/PAR-17-095.html>

CCSG Data Guide

<https://cancercenters.cancer.gov/GrantsFunding/DataGuide>

NCI's Organizations with Peer Review Funding List

<https://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C.pdf>