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PROTOCOL REVIEW COMMITTEE

Protocol Review and Monitoring System
Protocol Review Committee (PRC) Policies & Procedures

Policy Update:

This document outlines the Protocol Review and Monitoring System (PRMS) responsibilities of the University of Illinois Cancer Center. These responsibilities are primarily carried out by UI Cancer Center Protocol Review Committee (PRC). A summary of the changes is included here. All forms are found attached at the end of the document.

Version:	2.4
Last Reviewed:	6/24/2024
Effective Date:	06/24/2024

Cancer Center Approval

Title: Cancer Center Deputy Director

Approval Signature:

Electronically signed by: VK Gadi
Reason: requested
Date: Jun 24, 2024 12:57 CDT

Date: 06/24/2024

Protocol Review and Monitoring System (PRMS)
Protocol Review Committee (PRC) Policies & Procedures

Revision History

Version #	Date	Section	Details of Changes
2.4	6/24/2024	New Studies	Added submission and compliance requirements and further clarification to close non-compliant studies
2.3	04/25/2024	Introduction, New Study Submissions, New Study Review Outcomes, and PRC Membership and Meeting Organization	Added the NCI definition of Clinical Research; Added detail that the disease team minutes should have clear documentation regarding protocol prioritization; Added detail for studies who receive Modifications Required or Disapproved decisions; The PRC Chairs report to the Cancer Center Deputy Director
2.2	02/22/2024	Levels of Review (Expedited Review) and Protocol Prioritization	Added detail on other types of expedited reviews; Changed who is responsible for protocol prioritization
2.1	01/30/2024	PRC Membership and Meeting Organization and New Study Submissions (Exempt)	Addition of the process of how PRC committee members are trained; Clarification that single patient INDs are exempt
2.0	07/18/2023	New Study Submissions (Expedited Review) and Protocol Amendments	Removal of the exclusion of Expanded Access Protocols from PRC review and clarification that an amendment is to be submitted with the addition or deletion of study sites
1.9	11/15/2021	PRC Membership and Meeting Organization	Addition of a community engagement member to the committee
1.9	11/15/2021	Forms	Updating the Patient Advocate Form to also be the Community Engagement Member form
1.9	11/15/2021	New Study Submissions	Addition of Data Safety Monitoring form and protocol summary form as required submission documents for interventional studies.
1.8	07/01/2021	New Study Review Outcomes	The review outcome Disapproval now states that there is a 30 day timeframe for a re-review.
1.8	07/01/2021	PRC Membership and Meeting Organization	Addition of a Patient Advocate to the committee.
1.8	07/01/2021	Forms	Addition of a patient advocate reviewer form and minor revisions to initial reviewer form.

Protocol Review and Monitoring System (PRMS)
Protocol Review Committee (PRC) Policies & Procedures

1 Definitions

CCSG	Cancer Center Support Grant
CRLC	Clinical Research Leadership Committee
DSMC	Data and Safety Monitoring Committee
DSMP	Data and Safety Monitoring Plan
EAP	Expanded Access Protocol
IRB	Institutional Review Board
NCI	National Cancer Institute
PI	Principal Investigator
PRC	Protocol Review Committee
PRMS	Protocol Review and Monitoring System
UI Cancer Center	University of Illinois Cancer Center

2 Introduction

The PRMS responsibilities required for the CCSG are primarily carried out by the UI Cancer Center's PRC. The purpose of this policy is to document the review processes undertaken by the PRC.

The PRC (also known as a Scientific Review Committee) evaluates all clinical research studies undertaken by the UI Cancer Center and its affiliates and conducted by UIC faculty, involving patients with cancer or individuals at risk for cancer. The NCI defines clinical research as one of three categories below:

- Patient-oriented research: This type of research is conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual, tissue banking, and studies that do not require patient consent (e.g., retrospective chart reviews). Patient-oriented research includes:
  - Studies of mechanisms of human disease
  - Studies of therapies or interventions for disease
  - Clinical trials, and
  - Studies to develop new technology related to disease
- Epidemiological and behavioral studies: Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g. surveillance, risk assessment, outcome, environmental, and behavioral studies.
- Health services research: Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.

The Protocol Review Committee is responsible for:

- Undertaking scientific review of all new studies

- Assessing general feasibility, annual accrual expectations, and competing studies
- Assigning risk according to the UI Cancer Center's DSMP and informing the UI Cancer Center DSMC
- Reviewing all protocol amendments that affect study design
- Maintaining written records of all meetings
- Monitoring accrual and ongoing scientific relevance for all studies
- Requesting corrective action plans for poorly accruing studies and closing studies that do not meet accrual expectations

3 Procedures

3.1 New Studies

All research studies requiring PRC review must be submitted to PRC and approved prior to submission to the IRB. All new study applications are reviewed by PRC administrative personnel to determine what level of review is appropriate. Studies may receive full committee, expedited review, administrative review, or be deemed exempt from PRC review.

The PI and/or research team are required to maintain the study record in OnCore including but not limited to any change in accrual goals as reported to the IRB of record, change in anticipated primary completion date, updating the study status, and reporting NCI required data regarding accruals (birthdate/age, gender/biological sex, race, and ethnicity). Failure to respond to requests to update required OnCore elements after two notices, within 15 business days, will result in a disapproval for study continuance. The PI can appeal this decision through the PRC appeal process which can be found in Section 4.0 (PRC Appeal Process).

New Study Submissions

For new studies, the PI or Submitter creates a new study record via the ePRMS submission console using the OnCore Clinical Trials Management System (CTMS). In addition, the following documents must be uploaded to the record.

- Final Protocol
- Prospective hypothesis driven studies: Disease Team Minutes for the meeting where the study was approved when required (see UI Cancer Center Disease Team Policy)
    - Disease Team Minutes should include clear documentation justifying the reason for opening the study in the event of any study portfolio conflicts with other studies enrolling the same population of the study being submitted
- PI NIH Biosketch, if NIH Biosketch is not available a curriculum vitae (CV) may be substituted
- Protocol Supporting Documentation, this includes but is not restricted to: Scientific Approval Letter from designated site, Surveys, Questionnaires, etc.

Additional requirements for interventional studies only:

- UICC PRC Data & Safety Monitoring Plan (DSMP) Form: A study specific DSMP is required if the study is an Interventional clinical trial. If the study is a phase III investigator initiated

therapeutic clinical trial, the DSMP needs to include plans for an independent Data and Safety Monitoring Board (DSMB).
- Protocol Summary Form

Levels of Reviews

There are four levels of PRC review:

- Exempt
- Administrative
- Expedited
- Full Committee

Exempt from PRC Review

The following types of studies are exempt from PRC review.

- Retrospective chart review studies
- Institutional registries, databases, and serum and tissue banking protocols where there are no research hypotheses
- Single patient INDs

Exempt studies are not required to be entered into OnCore. If the study qualifies under the exempt criteria, email the protocol to the PRC administrative personnel for an exemption letter. If approved, the PRC administrative personnel will provide an exemption letter that must be included in the Initial IRB submission.

Administrative Review typically includes:

1. NCI-approved cooperative group studies (National Clinical Trials Network) and NCI Cancer Therapy Evaluation Program (CTEP)-approved studies.

2. Multi-site institutional trials previously approved by a PRMS from another NCI-designated Cancer Center. Documentation of the external PRC approval must be on file with the UICC PRC.

3. Prospective, hypothesis-driven, non-interventional studies (e.g., observational, ancillary, or correlative studies) that are not investigator initiated.

For studies meeting the administrative review criteria listed above, the PRC administrative personnel will review all submission materials and assure that the criteria above is met. If no substantive issues are identified during the administrative review, PRC administrative personnel will then generate an approval letter that is emailed to the PI. Administrative reviews are typically communicated within 3 business days of receipt. A summary report of all studies that received administrative review since the last PRC Full Committee is included in the agenda and noted in the minutes.

Expedited Review typically includes:

1. Investigator-initiated studies that have or will receive external peer-review and funding by an approved NIH peer-review funding organization prior to activation. Extramurally funded studies

that do not include a protocol as part of the peer-review process may, at the PRC Chair's discretion, undergo a Full Committee Review.

2. Prospective, hypothesis-driven, non-interventional studies (e.g., observational, ancillary, or correlative studies) that are investigator initiated.

3. Expanded Access Protocols (EAPs), that is industry-initiated protocols where the primary objective is to provide rapid access to an unapproved drug to patients [See also industry-initiated studies in Full Committee Review below]

4. Annual Continuation Reviews (see section 3.2) and replies to Response to Modification Required determinations (see section 3.1).

For studies that meet the expedited review criteria listed above, the PRC Chair will review all submission materials and perform an expedited review, assuring that conflicts with current studies do not exist, resources appear appropriate to implement and complete the study, and that appropriate data and safety monitoring and recruitment plans are in place. If no substantive issues are identified during the Chair's review, PRC administrative personnel will then generate an approval letter that is emailed to the PI. In the event that a conflict of interest exists and/or the Chair is an investigator on the study being reviewed, the Vice Chair will conduct the review. Expedited reviews are typically communicated within ten business days of receipt. A summary report of all studies that received expedited review since the last PRC Full Committee is included in the agenda and noted in the minutes.

Note that any of the above types of studies may, at the PRC Chair's (or Vice Chair's) discretion, be required to undergo a Full Committee Review.

Full Committee Review

Studies that do not meet criteria for administrative or expedited review or exemption will receive full committee review.

Studies eligible for full committee review typically include the following:

1. Interventional Investigator-initiated studies: These generally are studies developed by UI Cancer Center faculty with funding from the institution, a non–peer-reviewing agency, or industry. Multi-institutional investigator-initiated studies where the study PI is at another non–NCI-designated institution and the study has not undergone formal peer review (as outlined in the Expedited Review criteria above) also require full committee review.
2. Industry-initiated studies: The concept and protocol for these studies are developed by a company. There is an exception to this requirement for EAPs, since their primary objective is to provide rapid access to an unapproved drug to patients (see above).

Full committee review focuses on the scientific merit of the study, prioritization of the study within the larger portfolio, competing studies, and accrual feasibility. Committee members will address all scientific aspects of a proposed study according to defined review criteria, including but not limited to:

- The study addresses a relevant scientific question
- The primary and secondary objectives are scientifically sound
- The study design is appropriate to meet the objectives
- The response criteria and endpoints are clearly defined
- The sample size is appropriate to answer the question, accrual goals are clearly stated and the patient population is sufficient to meet accrual goals
- The data and safety monitoring plan is appropriate
- The early stopping rules are adequate and clearly described
- The investigator has an appropriate plan for the inclusion of women and minorities

Reviewers will also assign a level of risk to Investigator Initiated studies which will determine the recommended level of auditing and monitoring of the DSMC.

PRC Submissions for NIH JIT Requests and IRB Submissions for Core/Center Grants.

If a submission to the IRB is in response to an NIH Just In Time (JIT) request, then all documents and processes for both PRC and IRB review are required.

If the submission is for a Core/Center grant, a Training grant, a grant where human subject involvement will depend on the development or completion of instruments, procedures, or prior non-human studies, as defined by the IRB, or is for a grant submission that has not yet been approved for funding by a peer reviewing funding agency (grant is pending review) but the investigator needs to seek IRB approval, then the PRC will not review the application. However, a letter will be issued to the PI stating that the submission is granted an approval by the PRC *contingent* upon funding by the granting agency and approval by the IRB. However, prior to the involvement of human subjects, the use of identifiable subject information, and/or pilot testing of instruments or procedures, a protocol describing the human subjects' activities must be reviewed and approved through the appropriate review process described above.

Process for Protocols Included in Grant Submissions to Extramural, Peer Reviewing Agencies

If a grant submission has already been reviewed and approved for funding by a peer reviewing funding agency, an expedited approval letter from the committee will be issued to the PI provided the study has all of the required protocol elements.

Click this link to view organizations with Peer Review Funding Systems

Protocol Prioritization

NCI guidelines require that a mechanism be established within a cancer center for prioritizing competing research studies that may enroll subjects with similar eligibility criteria. At the UI Cancer Center studies are prioritized by PRC administrative staff upon submission and confirmed by the PRC reviewer. The PRC prioritizes studies utilizing the scoring scale below, with 1 representing the highest priority, and which mirrors the priorities of the UICC. This score is captured in the OnCore CTMS. The scoring system is based on protocol type, sponsorship, and potential for scientific impact. The PRC utilizes this score to prioritize studies on meeting agendas.

Table 1. Protocol Prioritization Scoring Scale

Study Originator	Study Type	Score
IIT	Treatment	1
NCTN	Treatment	2
Foundation or External IIT	Treatment	3
Industry	Treatment	4
IIT	Interventional	5
NCTN	Interventional	6
Foundation or External IIT	Interventional	7
Industry	Interventional	8
IIT	Non-interventional	9
NCTN	Non-interventional	10
Foundation or External IIT	Non-interventional	11
Industry	Non-interventional	12

Determination of Risk

Each UI Cancer Center study undergoes scientific review by the PRC, in part to ensure that procedures are in place to ensure the safety of subjects depending on the degree of risk of the study. The PRC assigns a category of risk to every UI Cancer Center investigator initiated clinical trial and the DSMC follows the plan of review for that category.

The purpose of assigning a level of risk (low, moderate, or high) is to ensure that data and safety monitoring activities are appropriate for the level of subject risk. In order to make a decision, the PRC reviews the following criteria:

- Expected duration of the study based on the study design and estimated rate of enrollment.
- Study population (e.g. children, pregnant women).
- Procedures to ensure the safety of subjects in accordance with the degree of risk.
- Methods to ensure the validity and integrity of the data, including adequate biostatistical design and appropriate data analysis.
- Adequate data management systems including case report form records and a plan for data collection.
- Procedures for reporting serious adverse events to the appropriate departments/committees (e.g. IRB, FDA, NIH).
- The number of sites involved in the clinical trial.
- The specific risks known to be associated with a particular treatment/intervention

The risk level determines the frequency of monitoring for a protocol, which may be altered (i.e., increased) as and if issues arise.

Definition of Risk Levels

There are three levels of risk that may be assigned: High, Moderate and Low. Each category is described below. Please reference the UI Cancer Center's DSMP for monitoring frequency based on risk assignment.

High Risk

Studies assigned to the high-risk category include any therapeutic investigator-initiated pilot, phase I, II, or trials involving IND/IDEs, investigator-initiated multi-center trials, as well as any research involving recombinant DNA molecules (gene transfer) and cell-based therapies. These clinical trials will be reviewed on a quarterly basis by the DSMC.

Moderate Risk

Studies assigned to the moderate-risk category include most investigator-initiated, single center, Phase I or II trials using FDA-approved, commercially available compounds. Moderate Risk trials will be reviewed biannually (every 6 months) by the DMSC.

Low Risk

Studies assigned to the low-risk category include investigator initiated non-therapeutic trials. Low risk trials will be reviewed annually by the DSMC.

Protocol Review and Response Expectations

Study submissions that have been received 13 BUSINESS days prior to the scheduled PRC meeting will be assigned to a minimum of 3 reviewers by the PRC Chair. Studies submitted after 13 business days will be assigned to the next scheduled PRC meeting.

- For treatment studies two reviewers **must be** treating physicians, and the third reviewer must be a statistician. Additional reviewers may be assigned as appropriate.
- For non-treatment studies, two researchers with relevant expertise may be assigned as reviewers, and the third reviewer must be a statistician.

Reviewers are required to complete PRC review forms (accessed in OnCore) prior to the PRC meeting in order for the protocol to be discussed and voted on at the meeting. If review forms are not completed prior to the meeting, the protocol may be tabled until the next PRC meeting, at the Chair's discretion.

The PRC review outcome will be emailed to the PI and the Submitter no later than ten business days following a meeting with an electronic copy of a signed letter containing a summary of the committee's deliberation and comments if applicable. Please note that after receiving the PRC decision letter the PI should provide a response within 15 business days for a "modifications required" outcome. If no response is received, the study will be disapproved at the discretion of the PRC Chair.

New Study Review Outcomes

Once the new study review is completed, the PRC administrative personnel will prepare a review outcome notification that will be issued to the PI and Submitter. Review outcomes include the following:

- Approved
  - The study is approved for activation as submitted and may proceed to the IRB. The PI and Submitter will receive an approval letter.
- Modification Required
  - The study review results in concerns that require a PI response which may include minor modifications to the study or study materials. PI and Submitter will receive a letter requesting a written response to the committee's required changes and a tracked change version of the protocol, if protocol modification(s) are made in response to required changes. Should the response be found to be satisfactory, as determined by the PRC Chair or the original reviewers, the PI and Submitter will receive a final approval letter. If the PI does not respond within 15 days of receiving PRC decision letter, the study will be disapproved at the discretion of the PRC Chair.
- Disapproved
  - The study does not satisfy the review criteria and significant revisions to the study are necessary. PI will receive a letter requesting a written response to the committee's required changes and a tracked change version of the protocol if protocol changes are made as part of the response. The study must be re-submitted and reviewed at a full committee meeting. If all concerns are addressed, the PI and Submitter will then receive a final approval letter.
  - If the PI does not respond to the PRC within 30 days of receiving such a PRC decision letter, the study may not be accepted, at the discretion of the PRC Chair.
  - Studies that are disapproved twice and subsequently resubmitted to the committee may not be accepted, at the discretion of the PRC Chair.

3.2 Annual Continuation Review and Accrual Monitoring

Annual Continuation Review

Evaluation of the scientific progress of studies and how they fit into overall progress in their specific area of research is important to ensure that the study is continuing to address an important scientific question.

Studies are reviewed annually from the date of PRC approval, however the PI and/or Submitter can request to reset the annual review date to one year post IRB approval.

The purpose of the annual continuation review is to:

1. Evaluate major developments that occurred in the scientific area that affect the specific objectives of the study
2. Determine if sufficient progress is being made, including accrual
3. Monitor changes in the study's priority
4. Summarize any interim analysis and any significant study outcomes (e.g. met DLT, met accrual on specific study arm)

Annual Continuation Review Submissions

For all annual continuation review submissions, PI or Submitter creates a continuation record via the ePRMS submission console using the OnCore CTMS.
Submission requirements:

- PRC Annual Continuation Review Form; please note all fields are required
- Current protocol

The annual continuation review submission must be submitted to PRC prior to the PRC expiration date each year until the study is permanently closed to accrual.

Annual Continuation Review Process

Annual continuation review submissions are reviewed by the PRC Chair and Vice Chair, except as described in administrative review below. PRC administrative personnel will review each annual continuation review submission for completion and once complete, forward it to the PRC Chair and Vice Chair for review via an expedited review process. The PRC Chair and Vice Chair have the prerogative to refer any annual continuation review submission for full committee review (for example if there have been substantial modifications to the original protocol (see Section 3.4)).

Accrual Monitoring is an integral part of the annual continuation review process and must follow the guidelines as outlined in section 3.3.

Annual continuation review submissions that qualify for administrative initial review are reviewed by the PRC administrative personnel. In addition, full committee or expedited studies that have had no changes during the course of the year will be administratively reviewed. The PRC administrative personnel will assure that all criteria are met, and that the submission is complete. PRC administrative personnel have the prerogative to refer any annual continuation review submission for expedited review by the PRC Chair and Vice Chair.

Annual Continuation Review Outcomes

After review by the PRC Chair and Vice Chair, PRC administrative personnel will either prepare a review outcome notification (approved for continuation or disapproved for continuation) or prepare the submission for full committee review. Review outcome notifications are issued to the PI and Submitter.

When a PI closes or terminates a protocol, the status must be updated in OnCore, and an electronic communication will be sent to PRC administrative personnel stating that the research is closed to accrual. A continuing review is no longer required when a study has been closed to accrual.

3.3 Accrual Monitoring

Accrual monitoring will be conducted for all active interventional studies semiannually. Prior to the accrual monitoring meeting, PRC administrative personnel will run a report identifying the status of all studies and their accrual. PRC administrative personnel will send out requests for justification of continuance to the PI of studies not meeting expected annual target goals (see below). The PI will be given 15 business days to respond. The PRC Chair will then review PI responses at the PRC meeting and determine if the study will remain open.

Target Accrual Reporting

At the time of initial PRC submission, the investigator is required to project the estimated total accrual and the estimated total duration of the study accrual. These projections will be utilized by the PRC for monitoring accrual progress.

Every 6 months, PRC administrative personnel generates a report identifying prospective interventional oncology studies that are actively enrolling cancer patients/subjects with the following fields:

- Protocol Number
- PI name
- Study title
- Indication if the study targets a rare cancer
- Date the study was opened to accrual
- Any temporary suspensions and date when trial was re-opened
- Gender distribution
- Race distribution
- Ethnicity distribution
- Research Center's (RC) anticipated (lower) target accrual
- RC anticipated duration for accrual
- RC total actual annual accrual to date
- Percent Accrued = $\frac{\text{RC total actual annual accrual}}{\text{RC Annual Accrual Goal}} \times 100$

For those studies where the *Percent Accrued to Date* falls below 50% of the projected annual accrual, PRC administrative personnel will issue a written notification requesting a response or justification from the PI. The PI shall be given 15 business days to respond to the notice with a specific plan to increase accrual. The PI's response will be reported to the PRC Chair approximately one month following the report's generation. The PRC Chair will determine if the PI's response is acceptable and whether the study may continue as planned, requires further justification or additional information, or will be closed to accrual. During the review period, PRC administrative personnel will also monitor those studies that have attained or exceeded their accrual goals. PRC administrative personnel will send a notice of acknowledgment to the PI that accrual monitoring has occurred and accrual goals have been met. For studies that have exceeded their goals, the PI will be advised to consider whether a modification request to applicable study sponsors and the IRB is warranted to increase accrual goals. The annual accrual goal may undergo a one-time change with justification to the PRC at the time of accrual monitoring.

Table 2. Summary of PRC Accrual Expectations and Action Guidelines

Study Accrual Status	Type of PRC Accrual Monitoring Review	PRC Actions
All Prospective Interventional Studies Involving Rare Cancers[1]	Annually	Approved for continuation if scientific aims remain relevant. Justification of continuation of studies with ≤1 accrual per year is required.
All Pediatric Prospective Interventional studies	Annually	Approved for continuation if scientific aims remain relevant. Justification of continuation of studies with ≤1 accrual is required. Pediatric studies with zero accrual or less than 50% will be exempt for maximum of 3 years. At the 2 year mark, a justification for continuance will be requested. At the 3 year mark the study will receive final warning for closure.
Interventional Studies opened < six months	Exempt	N/A
Interventional Studies opened > six months	*All Studies with the following accrual status are subject to PRC Accrual Review.* *See categories below for expected PRC actions*	
Percent Accrued to Date > 50%	Semiannually	Approved for continuation

[1] Please reference National Institutes of Health site for a list of rare cancers: https://rarediseases.info.nih.gov/diseases/diseases-by-category/1/rare-cancers

Percent Accrued to Date < 50%	Semiannually	1st Review: Contingently Approved. The PI will be informed that accrual will be closely monitored during the next quarter and if sufficient progress is not made, the PI will need to provide more justification and/or a revised corrective action plan. 2nd Review Should the PI either: - fail to provide a corrective action plan, *and/or* - fail to improve accrual, *and/or* - fail to demonstrate adequate screening activity then the PRC will require the PI to close the study. Should the PI: - Provide a corrective action response and/or demonstrate an improvement in the accrual and/or screening activities the accrual review may be approved. Decision to close study: PI will be requested to provide study closure documentation (communication with IRB and/or Sponsor).

3.4 Protocol Amendments

Protocol amendments for studies that have been reviewed by the PRC and affect the principal elements of the original protocol, including but not limited to: study rationale, response criteria, eligibility criteria, objectives, study design, addition or removal of study sites, treatment plan, sample size, stopping rules, or statistical plan, must be submitted to the PRC in concurrence with the IRB for review and approval. Amendments that do not impact the aforementioned areas do not require PRC approval.

Amendment Submissions

For all amendment submissions, PI or Submitter creates a change review record via the ePRMS submission console using the OnCore CTMS.
Submission requirements include:

- PRC Amendment Committee Amendment Review Form with summary and justification of changes
- Clean, revised protocol
- Track change version of protocol showing the changes in the amendment

Amendment Review Process

PRC administrative personnel will review each amendment submission for completion and once complete, assign it to the PRC Chair or Vice Chair for review, except as described in administrative review below. The PRC Chair and Vice Chair have the prerogative to defer any amendment for full committee review.

Amendment review submissions that qualify for initial administrative review are reviewed by the PRC administrative personnel. The PRC administrative personnel will assure that all criteria are met, and that the submission is complete. If there is an addition or removal of a study site the PRC administrative personnel will confirm whether the risk level of the protocol has changed, and if so, notify the DSMC coordinator. PRC administrative personnel have prerogative to refer any amendment review submission for expedited review by the PRC Chair and Vice Chair.

Amendment Review Outcomes

After review by the PRC Chair or Vice Chair, PRC administrative personnel will either prepare a review outcome notification, or prepare the submission for full committee review, depending on the outcome. Review outcomes include, approval, modifications required or disapproval. A review outcome notification of “approval” is issued to the PI and Submitter. A review outcome notification of “modifications required” will include an explanation of which revisions were not acceptable and why and may contain suggestions as to how the PI can make the revisions acceptable.

4.0 PRC Membership and Meeting Organization

The PRC meets biweekly. Cancellations or modifications may be allowed for holidays and other unforeseen circumstances and will be communicated Cancer center-wide. Meetings may be

recorded to assist with minutes and documentation. Meeting minutes are shared with the PRC Chair and Vice Chair, then are sent for approval to the Cancer Center Deputy Director.

Member Anonymity

The identity of the PRC members reviewing a particular trial will remain anonymous to the submitter of the protocol and to the general UI Cancer Center community, unless the reviewer requests to contact the submitting PI directly. If the submitting PI has questions or concerns about PRC comments, they are asked to submit these questions to the PRC administrative personnel who will reach out to the appropriate committee member for clarification. PRC administrative personnel will respond to the PI without revealing the identity of the reviewers.

Conflicts of Interest

A PRC member who is the PI of a study being reviewed at a PRC meeting must be recused from the meeting during the review, discussion, and voting on the protocol. A PRC member who is a Co-Investigator of a study being reviewed at a PRC meeting is allowed to be present for discussion, however he or she must abstain from voting. A PRC member that has a financial conflict of a study being reviewed at a PRC meeting must be recused from the meeting during the review, discussion and voting on the protocol.

PRC Membership

PRC membership will include broad representation across medical disciplines in order to provide the highest quality study reviews. The Cancer Center Director and the Cancer Center Deputy Director shall identify and appoint established researchers as PRC Chair and Vice Chair of the PRC, ideally two senior faculty representing different disciplines. Potential PRC members are identified by the Cancer Center Deputy Director and the PRC Chair and Vice Chair and presented for review and approval by the Cancer Center Director. PRC faculty members must be members of the Cancer Center. The following minimum experience criteria are expected: to be at least 3 years post-completion of fellowship, and have experience as PI through completion of at least 1 clinical study and publications on research study outcomes. The PRC faculty membership should be comprised of 60% senior faculty (full professor and associate professor). Junior faculty may be appointed, but must meet minimum experience criteria. The PRC voting membership also includes a biostatistician, a patient advocate, and a community engagement member.

PRC membership shall be a three year commitment with a two term maximum. Members are expected to attend 75% of meetings annually or membership may be revoked at the Chair's discretion.

Members of the PRC may not serve simultaneously on the IRB, the DSMC, or as Clinical Trials Office Medical Director, Associate Director of Clinical Research, or Cancer Center Deputy Director.

The PRC Administrator trains all new members on the review process and provides them with a copy of the PRC Policy outlining their responsibilities. New members are then trained on how to conduct scientific reviews by the PRC Chair.

Initial and Ongoing Training Quorum

Meeting quorum is 50% of committee membership and must include the PRC Chair or Vice Chair and one biostatistician member.

Responsible Personnel

The Cancer Center Deputy Director, PRC Chair, Vice Chair and PRC administrative personnel are responsible for the execution of these policies and procedures. The PRC Chair and Vice Chair report directly to the Cancer Center Deputy Director.

PRC Appeal Process

PIs can appeal any PRC decision by submitting a written request for an additional review to the PRC. However, there is no appeal process beyond the PRC and the final PRC decision cannot be overturned. The protocol may be resubmitted at another time as a new protocol, provided there are substantial changes and/or modifications.

UI Cancer Center PRC Policies Version 2.4

Final Audit Report 2024-06-24

Created:	2024-06-24 (Central Daylight Time)
By:	Justin Davis (davisj02@uic.edu)
Status:	Signed
Transaction ID:	CBJCHBCAABAAdvCOO_OOgpWbQObd4BpBJTawBkSfeeKR
Number of Documents:	1
Document page count:	17
Number of supporting files:	0
Supporting files page count:	0

"UI Cancer Center PRC Policies Version 2.4" History

Document created by Justin Davis (davisj02@uic.edu)
2024-06-24 - 12:21:50 PM CDT- IP address: 73.9.84.109

Document emailed to VK Gadi (vkgadi@uic.edu) for signature
2024-06-24 - 12:30:32 PM CDT

Email viewed by VK Gadi (vkgadi@uic.edu)
2024-06-24 - 12:31:08 PM CDT- IP address: 128.248.255.236

Agreement viewed by VK Gadi (vkgadi@uic.edu)
2024-06-24 - 12:31:27 PM CDT- IP address: 128.248.255.236

VK Gadi (vkgadi@uic.edu) authenticated with Adobe Acrobat Sign.
Challenge: The user clicked on the signature field: 'Signature 1'.
2024-06-24 - 12:57:43 PM CDT

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