UNIVERSITY OF ILLINOIS CANCER CENTER
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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.

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Cancer Center Approval

Title: Associate Director of Clinical Sciences

Approval Signature: **Date:**

John H. Stewart, III, MD

July 1, 2021

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

Revision History

Version #	Date	Section	Details of Changes
1.8	07/01/2021	Introduction & Procedures	The Introduction and Procedures section has updated verbiage that now includes PRC review of all clinical research studies undertaken by the UI Cancer Center and its affiliates and conducted by UIC faculty.
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
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 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 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.

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)
- 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.

Interventional studies only: UICC PRC Data & Safety Monitoring Plan (DSMP) For Interventional Studies 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).

Levels of Reviews

There are four levels of PRC review:

- Administrative
- Expedited
- Exempt
- Full Committee

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 Principal Investigator. 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.

For studies meeting the expedited review criteria listed above, the PRC Chair will review all submission materials and give a rapid 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 Principal Investigator. In the event 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.

Exemptions

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 subject compassionate use or emergency use protocols where there are no research hypotheses

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 for exemption the PRC administrative personnel will provide an exemption letter that must be included in the Initial IRB submission.

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 Principal Investigator 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.

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.

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 protocol prioritization is set by the Disease Teams before submission to the PRC. This score will be captured in the OnCore CTMS. The scoring system is based on protocol type, sponsorship, and potential for scientific impact. The PRC will utilize this score to prioritize studies on a meeting agenda.

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
NCTN	Non-interventional	9
IIT	Non-interventional	10
Foundation or External IIT	Non-interventional	11
Industry	Non-interventional	12

Determination of Risk

Each UI Cancer Center investigator-initiated 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) to an UI Cancer Center investigator-initiated trial 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.

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 will provide a response within 15 business days for a "modifications required" outcome. If no response is received, the study will be disapproved.

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 concerns. 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 concerns, and 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 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 PRC expiration 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.

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 is targeted for a rare cancer and/or is a molecular targeted therapy
- Date the study was opened to accrual
- Any temporary suspension and re-open dates
- 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. Annual accrual goal may undergo a one-time change with justification to the PRC at the time of accrual monitoring.

Table 3. 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] and Molecular targeted therapies	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 full committee and affect the principal elements of the original protocol, including but not limited to: study rationale, response criteria, eligibility criteria, objectives, study design, 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

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. 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 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 Associate Director of Clinical Research.

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 Associate Director of Clinical Research 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 Associate Director of Clinical Research and the PRC Chair and Vice Chair and presented for review and approval by the Cancer Center Director. The PRC must consist of members with active membership with the Cancer Center. The PRC must include representation from biostatistics, and a patient advocate. The PRC must be comprised of 60% senior faculty (full professor and associate professor). Junior faculty may be appointed but must meet minimum experience criteria including: 3 years post-fellowship completion, experience as PI through completion of at least 1 study, accrual of 5 to 10 patients to studies per year, and publications on research study outcomes.

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 DSMC, or as the Clinical Trials Medical Director or as the Associate Director of Clinical Research.

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 Associate Director of Clinical Research, 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 Associate Director of Clinical Research.

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.

Protocol Review Committee (PRC)
Reviewer Form

PRC #
Principal Investigator:
Protocol Title:
I have reviewed the OnCore record: ☐ No ☐ Yes
Briefly describe the objectives of the study, the patient/subject population, the type of intervention and the scientific rationale for the study:

Protocol Review Committee (PRC)
Reviewer Form

Is the research question well defined, including the objective outcome measures? Will the data provide sufficient information to answer the research question(s)?
Are the key sections of the protocol (background, eligibility criteria, study design, study calendar, methodology, etc.) written clearly and adequately so as to answer the study objectives?
Describe any questions you have regarding competing studies, prior accrual history by the PI, or other issues affecting the ability to recruit to this study.
Are there any barriers in the eligibility criteria or study design that may impact the enrollment of underrepresented populations?

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Protocol Review Committee (PRC)
Reviewer Form

Is/Are the investigator(s) qualified to conduct the research?	
Are there any other issues and/or study flaws that need to be addressed?	
Does the protocol have adequate safety monitoring?	☐ **No** ☐ **Yes** ☐ **Not Applicable**
Is this study low, medium or high risk? **<u>Definition of Risk Levels</u>** There are three levels of risk that may be assigned: High, Moderate and Low. Each category is described below. *High Risk* Studies assigned to the high-risk category include any therapeutic investigator-initiated pilot, phase I, or phase II trials, or trials involving IND/IDEs, investigator-initiated multi-center trials, as well as any research involving recombinant DNA molecules (gene transfer) or 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 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.	☐ **Low** ☐ **Medium** ☐ **High**
Preliminary Recommendation: ☐ **Approved** ☐ **Modifications Required** ☐ **Disapproved**	

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PRC Meeting Date:
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PROTOCOL REVIEW COMMITTEE

Protocol Review Committee (PRC)
Biostatistics Reviewer Form

PRC #
Principal Investigator:
Protocol Title:
Are the research questions well defined, including objective outcome measures? Will the data collected provide information to answer the research question?
Is the design of the study appropriate? Have issues relating to patient drop out, ineligibility, or patient screening? .
Will the proposed data and analyses answer the primary and secondary aims of the study?
Is there an appropriate justification of sample size? For power calculations, is the effect size to be detected reasonable?

Protocol Review Committee (PRC)
Biostatistics Reviewer Form

Are there appropriate early stopping rules/ interim analysis plans for safety, futility and/or efficacy?

Are there any additional areas for concern regarding study design?

Preliminary Recommendation:
☐ **Approved** ☐ **Modifications Required** ☐ **Disapproved**

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Protocol Review Committee (PRC)
Patient Advocate Reviewer Form

PRC #
Principal Investigator:
Protocol Title:
I have reviewed the OnCore record: ☐ No ☐ Yes
Describe any questions you have regarding competing studies, prior accrual history by the PI, or other issues affecting the ability to recruit to this study.
Are there any barriers in the eligibility criteria or study design that may impact the enrollment of underrepresented populations?
Are there any issues and/or study flaws that need to be addressed?
Preliminary Recommendation: **☐ Approved ☐ Modifications Required ☐ Disapproved**

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PROTOCOL REVIEW COMMITTEE

Protocol Review Committee (PRC)
Administrative Reviewer Form

PRC #
Principal Investigator:
Protocol Title:
I have reviewed the OnCore record (refer to Appendix 1): ☐ **No** ☐ **Yes**
Review Type: ☐ **Initial Review** ☐ **Continuing Review** ☐ **Amendment Review**
Administrative Review Category: ☐ **NCI-approved cooperative group study (National Clinical Trials Network) or NCI Cancer Therapy Evaluation Program (CTEP)-approved study** ☐ **Multi-site institutional trial previously approved by a PRMS from an NCI-designated Cancer Center.** ☐ **Prospective, hypothesis-driven, non-interventional study (e.g., observational, ancillary, or correlative studies) that is not investigator initiated.** ☐ **Continuing or Amendment Reviews with no changes to the study protocol but not currently enrolling.**
Are there any barriers in the eligibility criteria that may impact the enrollment of underrepresented populations?
Are there any other issues and/or study flaws that need to be addressed?

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Protocol Review Committee (PRC)
Administrative Reviewer Form

Does the protocol have adequate safety monitoring?	☐No ☐Yes ☐Not Applicable
Is this study low, medium or high risk? **Definition of Risk Levels** **There are three levels of risk that may be assigned: High, Moderate and Low. Each category is described below.** **High Risk** **Studies assigned to the high-risk category include any therapeutic investigator-initiated pilot, phase I, or II trials, or trials involving IND/IDEs, investigator-initiated multi-center trials, as well as any research involving recombinant DNA molecules (gene transfer) or 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 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.**	☐Low ☐ Medium ☐High
Preliminary Recommendation: ☐Approved ☐Modifications Required ☐Disapproved	

For Office Use Only:
PRC Meeting Date
Agenda #

UNIVERSITY OF ILLINOIS CANCER CENTER
Community to Bench

PROTOCOL REVIEW COMMITTEE

Protocol Review Committee (PRC)
Administrative Reviewer Form

Appendix 1: What to Check in OnCore

- Protocol Type: Review for appropriate coding
- DT4 Type: Review for appropriate coding
- Required Documentation:
    - Final protocol
    - Disease team minutes
    - NIH Biosketch/ CV
    - Supporting documentation
    - UICC Data Safety Monitoring Plan (DSMP) if applicable
- Principal sponsor: Ensure that a principal sponsor is listed

OL REVIEW COMMITTEE AMENDMENT FORM

Instructions: Please attach the completed form to the ePRMS submission.

1 Study Information

IRB Number:

PRC Number:

Protocol Title:

2 Amendment Information

Scientific amendments to protocols originally reviewed and approved by UI Cancer Center Protocol Review Committee (PRC) require additional PRC review and approval. The applicable sections of the protocol are listed below; please indicate the section(s) of the protocol that has been amended and provide a description of the amendment in the box below.

☐ Objectives

☐ Research Plan/Study Design

☐ Eligibility

☐ Statistical Considerations

☐ Other

Amendment Description:

3 PI Acknowledgment

☐ By clicking this box the Principal Investigator acknowledges that the information provided above is accurate.

********** **For Office Use Only** **********

4 PRC Decision

☐ Approved

☐ Modifications Required

☐ Disapproved

PRC Reviewer Comments:

UNIVERSITY OF ILLINOIS CANCER CENTER
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PROTOCOL REVIEW COMMITTEE CONTINUING FORM

Instructions: Please attach the completed form to the ePRMS submission.

1 Study Information

IRB Number:

PRC Number:

Protocol Title:

2 Accrual

What is the annual target accrual for this institution? _____

How many subjects have been consented in the previous year? _____

What is the date of the last patient on study? _____

What barriers have there been to accruing subjects on this trial? Have there been any amendments or other changes made to improve accrual?

Any suspensions of the protocol in the last year? _____

3 Study Progress

Please respond to the following questions with respect to the previous year.

Has there been any change in the oncology field that would negate the rationale or validity of the study? Please explain in 2-3 sentences.

Do you have any concerns about the timely completion of the study? Please explain.

4 Study Amendments

Have all protocol amendments that affect study design been submitted and reviewed by the PRC?

Yes ☐ No ☐

5 PI Acknowledgment

☐ By clicking this box the Principal Investigator acknowledges that the information provided above is accurate.

********** **For Office Use Only**********

6 PRC Decision

☐ Approved

☐ Modifications Required

☐ Disapproved

PRC Reviewer Comments:

UNIVERSITY OF ILLINOIS CANCER CENTER
Community to Bench

PROTOCOL REVIEW COMMITTEE DATA & SAFETY MONITORING PLAN (DSMP) FOR INTERVENTIONAL STUDIES FORM A

PI Name: _____ Protocol ID: _____

Study Title: _____

1. **Indicate the entity that will monitor the study data for safety:**

   - ☐ Investigator: complete 3-6 below
   - ☐ Individual monitor independent of the study team (such as sponsor's medical monitor): complete 3-6 below
   - ☐ Data Safety Monitoring Board or Committee (DSMB/C): Required for phase 3 studies, see #2 below
   - ☐ UICC Data and Safety Monitoring Committee (DSMC): Required for UIC investigator initiated interventional studies with no external DSMB, leave the remainder of the form blank

2. **If the study is being monitored by a DSMB, attached the DSMB charter or, if the study is NIH funded, the DSMP submitted to NIH. A DSMB charter should, at a minimum, contain the following information:**

   - A list of the DSMB members and a description of the DSMB composition
   - Meeting frequency, structure and procedures
   - A description of to whom, how, and with what frequency findings will be communicated
   - A description of the safety reporting process
   - Procedures for stopping rules and conducting interim analyses, as required by the protocol

PROTOCOL REVIEW COMMITTEE DATA & SAFETY MONITORING PLAN (DSMP) FOR INTERVENTIONAL STUDIES FORM A

Please complete the following if the study is not being monitored by a DSMB, including the UICC DSMC:

3. If known, list the monitor(s) in the table below. If not known, provide a general description of the expertise of the anticipated monitor(s).

Name/Credentials	Role in Study Monitoring	Expertise	Title/Organization

General description if individuals monitoring not known:

4. Describe the roles of the investigators, research coordinators, sponsor, monitoring entity, statistical consultant, etc. in gathering and monitoring the data, specifically addressing the following responsibilities:

a. Who records the data?
b. Who verifies data accuracy, by what method, and how frequently (examples: double data entry, outside audit, visual verification)?
c. Who verifies that procedures are conducted per the approved protocol?
d. Who conducts periodic assessments?
e. Who will evaluate events to determine if any represent unanticipated problems involving risks to subjects or others and the appropriate action as a result of those events?
f. How will confidentiality be maintained?
g. How will the data be evaluated and by whom?

5. **Describe the data and/or events that will be monitored, assessed, and reported to/by the monitoring entity and indicate the frequency with which the monitoring entity will review and assess the data and/or events and the procedures and methods the monitoring entity will use to evaluate the data and/or events, such as statistical analysis.**

6. **Describe the criteria and plan for taking action in response to monitoring entity findings, such as reporting, stopping rules, or implementing protocol changes.**