These modified policies and procedures follow the 2016 Cancer Center Support Grant (CCSG) guidelines for NCI-designated cancer centers. The NCI guidelines require cancer centers to have a qualified scientific review and monitoring committee with sufficient size and breadth of expertise to conduct a critical, fair review of all clinical research protocols comprising the cancer center.

The PRC is a multidisciplinary committee of at least 15 full members. A meeting quorum is declared when six full members are present, and a minimum of two are practicing clinicians. Should specific scientific expertise be required, ad hoc scientists or clinicians will be utilized per the PRC Chairs’ discretion. The PRC meets twice each month as a full committee. The PRC Executive Committee meetings occur weekly. The meeting schedule is posted on the Cancer Center web site: https://cancer.uillinois.edu/researchers-providers/clinical-trials/protocol-review.

PRC reviews take the place of departmental reviews for researchers conducting oncology research at University of Illinois at Chicago (UIC). Researchers submitting protocols to the PRC are expected to complete all required forms for the PRC. PRC reviews apply to studies with human subjects only.

1.0 Function of Protocol Review Committee

1.0.1. Conduct a full scientific review of all new investigator-initiated cancer research not undergoing peer review and supported by NIH mechanisms or NCI CTEP including basic, clinical, cancer control, and population research specified in section 3.0.

1.0.2. Conduct a feasibility review of new and continuing cancer clinical trial protocols that have already been peer reviewed and supported by NIH mechanisms and clinical research protocols approved by NCI’s CTEP.

1.0.3. Assist PIs with resubmission by providing written reviews with constructive and clear feedback.

1.0.4. Prioritize competing protocols from all sources, including those initiated at UI (University of Illinois) and those initiated by cooperative groups and industry.

1.0.5. Monitor all clinical cancer research protocols for sufficient progress, including adequate accrual rates. Terminate cancer clinical protocols not achieving scientific and accrual goals.

1.0.6. Monitor all clinical protocols for compliance with all the requirements established by the regulatory bodies such as the FDA and CIRB guidelines for toxicity reporting, definition of outcomes, definitions of response/progression, relapse, and adequacy of a trial.
1.0.7. Review and recommend changes regarding PRC function, policies, and procedures to the Cancer Center Clinical Research Executive Committee which is called the Cancer Center (Clinical Trials Office) CTO Executive Advisory Committee. After approval by the Cancer Center Clinical Research Executive Committee, appropriate changes will be executed.

Note: PRC will not make a determination based on informed consent and HIPAA documents as these are covered under IRB review. The PRC reviewers may provide non-binding suggestions to the PI related to informed consent and HIPAA.

2.0 Protocols Not Required for Review by the PRC
2.0.1. Single case compassionate use protocols.
2.0.2. Treatment/management guidelines not asking a research question.
2.0.3. Surveys of healthy subjects and the general population and population-based studies that do not involve UI patients, patient tests, drugs or procedures, and/or do not have endpoints related to cancer.
2.0.4. Secondary analysis of registry data.
2.0.5. Studies which have received exemption determination from the Office for the Protection of Research Subjects/Institutional Review Board (OPRS)/(IRB) at the University of Illinois.

3.0 New Protocols Eligible for Review by the PRC
3.0.1. All new cancer-related studies initiated at UI will have a full review (scientific and feasibility) by PRC in parallel to IRB submission. However, approval from the PRC is required before a new study can be IRB approved.

3.0.2. Any clinical cancer research at University of Illinois at Chicago (UIC) or Jesse Brown Veterans Affairs Medical Center (JBVAMC) involving UIC faculty and dealing with human cancer subjects.

3.0.3. All retrospective chart reviews of UIC patients with endpoints related to cancer.

3.1 Submission Process for New Protocols
3.1.1. For the PRC, submit all required documents using the OnCore Clinical Trials Management System (CTMS). The ePRMS Submission Console Initial Review form should be completed. One copy of the most current version of the protocol should be submitted to the PRC. An NIH Biographical Sketch (Biosketch) for the Principal Investigator (PI) of a study should be submitted. For those PIs lacking an NIH Biosketch, a curriculum vitae (CV) may be substituted. All three documents should be submitted to the PRC at the same time as submission to the IRB.

PIs are strongly encouraged to consult with a statistician prior to original submission. Michael L. Berbaum, Ph.D. from the department of Epidemiology and
Biostatistics of the School of Public Health as well as the Biostatistics Shared Resource Design & Analysis Core of the Cancer Center is available to provide statistical help to all PIs (312-413-0476).

3.2 Review Process for New Protocols

3.2.1. The PRC Manager in conjunction with a PRC Chair assigns all new cancer-related studies initiated at UIC or by UIC faculty to a primary and if needed a secondary reviewer. Cooperative group sponsored studies only require a primary reviewer; all other sponsor type studies require both a primary and secondary reviewer. Feasibility of trials which are not managed by the Cancer Center Clinical Trials Office (Non-CTO) trials will be evaluated by the PRC. Studies which are managed by the Cancer Center Clinical Trials Office (CTO) will initially be assessed for feasibility by the CTO Medical Director prior to review by the PRC. In general, the review process follows the guidelines set forth by various NIH study sections. If appropriate, a biostatistician will also be assigned. When review by a biostatistician is required, these factors will be evaluated: 1) The endpoints of the study; 2) Patient characteristics that may affect response; 3) The design of the study; 4) Sample size and statistical power to test the hypothesis; 5) A plan for data management; 6) Method(s) for data analysis; 7) Criteria for stopping the trial. When the biostatistician does not approve the statistical component of a given proposal, the PRC Manager will arrange a meeting between the biostatistician and the PI to clarify the concerns noted by the biostatistician so a revised proposal can be submitted within a reasonable time frame.

The committee recognizes that retrospective studies are often hypothesis generating rather than hypothesis driven. The committee requires that investigators provide description of the statistical methods to be used. The committee understands that this may be limited to descriptive statistics. Although precise analysis of the number of patients to be studied is not needed to initiate retrospective studies, please note that studies of conditions with low incidence at UIC may be deemed not feasible.

3.2.2. The PRC makes a determination and assigns a merit descriptor based on:
   • Clarity of presentation
   • Rationale: Sufficient material is included to justify the proposed protocol.
   • Research objectives: The primary and secondary objectives are clearly stated and reasonably achievable by the study.
   • Eligibility and study requirements: An appropriate study population is clearly defined and feasible.
   • Treatment or study plan: Protocol treatment is clearly specified, as are modifications to be made on the basis of toxicity, modifications which may be made at the discretion of the PI, and criteria for removing a patient from protocol treatment.
3.2.3. Outcomes from initial PRC review:

- **Approved**: Approved for opening to accrual contingent upon obtaining IRB approval and completion of all other protocol activation steps; approved by the full PRC.
- **Modifications Required**: PI needs to address minor issues before approval is granted. A PRC Chair, or a designee will provide final approval. Per a PRC Chair’s discretion, the protocol may be sent back to the original reviewer(s) for approval of the changes made by the PI.
- **Deferred Due to Scientific Reason**: There are sufficient problems with the protocol therefore substantial revisions and formal reconsideration by the PRC is required. The PRC members will try to assist the PI(s) in revising the proposal for resubmission. The final decision will be made by the full PRC.
- **Disapproved**: There are significant problems with the protocol therefore this study cannot be submitted to the committee for review.

### 4.0 Continuing Protocols Eligible for Review

4.0.1. For the PRC, submit all required documents using the OnCore Clinical Trials Management System (CTMS). The ePRMS Submission Console Continuation Review form should be completed for all cancer studies. One copy of the most current version of the protocol should be submitted. Both documents should be submitted to the PRC at the same time as submission to the IRB before the end of the PRC yearly review expiration period.

4.0.2. At the time of the yearly continuing review, the PRC Manager will examine the accrual for the study over the past year prior to a PRC Executive Committee meeting. If the accrual over the past year is less than 30% of the PI’s anticipated yearly accrual goal listed as the RC Annual Accrual Goal in OnCore, the PRC Manager will query the study requesting the PI to explain the poor accrual. During a PRC Executive Committee meeting, a PRC Chair will examine the accrual for the study and the PI’s rationale for poor accrual if a study had poor accrual over the past twelve months. The study will be monitored and reviewed during the PRC Executive Committee meetings the following year. If accrual has not improved, a PRC Chair could recommend termination of the study.

4.0.3. A continuing review is no longer required when accrual is closed.

4.0.4. If a study is suspended at the time of continuing review, the ePRMS Submission Console Continuation Review form should be completed for all cancer studies. One copy of the most current version of the protocol should be submitted. A rationale justifying the suspension status should be submitted. All three documents should be submitted to the PRC at the same
time as submission to the IRB before the end of the PRC yearly review expiration period.

4.1 Review Process for Continuing Protocols

4.1.1. A PRC Chair will complete the continuing review for a PRC Executive Committee meeting. If needed, a PRC Chair will assign the continuing review to another reviewer or a biostatistician. The reviewer’s critique will be available to PRC members for discussion at the next full PRC meeting.

4.1.2. Factors considered by the PRC during the annual continuing review:
- Accrual
- Toxicity
- Adherence to regulatory guidelines and protocol
- Continued scientific merit (only for investigator-initiated and industry sponsored protocols not already peer reviewed by a NIH or NCI mechanism).

4.1.3. Outcomes from the PRC continuing review:
- Approved: Approved for continuation contingent upon IRB approval.
- Modifications Required: PI needs to address minor issues before approval is granted. The PRC Chair or a designee will provide final approval. Per the PRC Chair’s discretion, the protocol may be sent back to additional reviewers for approval of the changes made by the PI.
- Deferred Due to Scientific Reason: There are sufficient problems with the protocol therefore substantial revisions and formal reconsideration by the PRC is required. The PRC members will assist the PI(s) in revising the proposal for resubmission. The final decision will be made by the full PRC.
- Recommend Closure: The protocol is not approved for continuation due to any of these circumstances:
  - Subject accrual has been met and there is not a requirement for follow-up.
  - New scientific findings have obviated the need for the protocol.
  - Conduct of the research is of such poor quality as to make the findings of the protocol questionable.
  - Patient accrual expectations have not been met.
- Disapproved: There are significant problems with the protocol therefore this study cannot be submitted to the committee for review.

5.0 Amendments to Protocols

5.0.1. The PRC and the UIC IRB will conduct a parallel review of two types of amendments for all trials:
- Changes to the research protocol, including subject enrollment
- Changes to the research principal investigator or co-investigators
For the PRC, submit all required documents using the OnCore Clinical Trials Management System (CTMS). The ePRMS Submission Console Change Review form should be completed. One copy of the most current version of the protocol should be submitted to the PRC. Lastly, if there is a change in PI, a NIH Biosketch for the new Principal Investigator (PI) of a study should be submitted. For those PIs lacking a NIH Biosketch, a curriculum vitae (CV) may be substituted. All two or three documents should be submitted to the PRC at the same time as submission to the IRB.

A PRC Chair will complete the amendment review for a PRC Executive Committee meeting. If needed, a PRC Chair will assign the amendment review to another reviewer or a biostatistician. The reviewer’s critique will be available to PRC members for discussion at the next full PRC meeting.

5.0.2. All other amendments should be submitted to the IRB for review and approval per the IRB’s policies.

5.0.3. Outcomes from the PRC amendment review:
- **Approved**: Approved for continuation contingent upon IRB approval.
- **Modifications Required**: PI needs to address minor issues before approval is granted. A PRC Chair or a designee will provide final approval. Per a PRC Chair’s discretion, the protocol may be sent back to additional reviewers for approval of the changes made by the PI.
- **Deferred Due to Scientific Reason**: There are sufficient problems with the protocol therefore substantial revisions and formal reconsideration by the PRC is required. The PRC members will assist the PI(s) in revising the proposal for resubmission. The final decision will be made by the full PRC.
- **Recommend Closure**: The protocol is not approved for continuation due to any of these circumstances:
  - Subject accrual has been met and there is not a requirement for follow-up.
  - New scientific findings have obviated the need for the protocol.
  - Conduct of the research is of such poor quality as to make the findings of the protocol questionable.
  - Patient accrual expectations have not been met.
- **Disapproved**: There are significant problems with the protocol therefore this study cannot be submitted to the committee for review.

6.0 Notification of PRC Review Outcome
The PRC review outcome will be emailed to the PI and their research coordinator no later than two working days following a meeting with an electronic copy of the signed approval letter and PRC Reviewer form(s). A hard copy of the signed approval letter and PRC Reviewer form(s) will be delivered to the PI upon request.
When the protocol is approved, the PI will include the PRC letter and PRC Reviewer form(s) with the IRB submission. If the PRC letter and PRC Reviewer form(s) are not included, the IRB may return the IRB submission as incomplete.

When the protocol is not approved, the PI has the option of contacting the PRC Manager for guidance with resubmission. When the protocol is resubmitted, it must be returned with the original assigned PRC or IRB number.

When the PI is not planning to respond to a PRC decision of "modifications required" or "deferred due to scientific reason," the PI is required to notify the PRC in writing.

### 7.0 PRC Prioritization Procedure

The PRC will give first priority to meritorious clinical protocols. If there are two or more conflicting proposals or there is evidence of possible overlap between two proposals, the prioritization schema will strictly depend on scientific merit, the possibilities of answering logical questions within a reasonable timeframe, as well as the impact on the medical and general public. The mechanism of prioritization will be based on a plan devised by the Cancer Center Clinical Research Executive Committee in consultation with the PRC and will periodically be assessed to maintain impartiality and objectivity.

### 8.0 Termination of a Protocol by PI

When a PI closes or terminates a protocol, a letter should be sent to the PRC stating that the research is no longer ongoing. This letter should be uploaded into the OnCore CTMS system using the PC Console Documents/Info section.

### 9.0 Reportable Events-Adverse Events (AE)/Serious Adverse Events (SAE) by PI

The PI of an ongoing study is responsible for reporting all reportable events to the UIC IRB. Refer to the following for additional guidance on reportable events that may pertain to your study protocol:

- UIC IRB: research.uic.edu/compliance/irb
- Your study protocol
- The sponsor’s Drug and Safety Monitoring Board (DSMB)
- Food and Drug Administration (FDA): www.fda.gov/
- University of Illinois Cancer Center Data and Safety Monitoring Committee (DSMC)

### 10.0 PRC Appeal Process

PIs can appeal a PRC decision of “recommend closure” or “disapproved” by submitting a written request for an additional review to the PRC. After the
additional review, the PRC can reverse the decision, ask for further revisions, call for an external review, or ratify the original decision.

11.0 PRC Membership
Protocol Review Committee members are required to attend 50% of all the full PRC meetings every year. PRC members are required to review approximately twelve (12) protocols every year, depending on the quantity of protocols received by the PRC. PRC members are required to attend the meeting when they are an assigned reviewer for a study. If a PRC committee member is unable to complete a review by the Tuesday prior to the Thursday meeting when the study is on the agenda, the committee member is required to provide justification to a PRC Co-Chair. PRC members must notify the PRC Manager one to two weeks prior to the expected attendance via e-mail if the member is unable to attend the full PRC meeting.

12.0 Process for Revising PRC Function, Policies, and Procedures
Individuals proposing changes regarding the PRC function, policies, and procedures are required to contact the PRC Manager by sending an e-mail regarding the proposed change and a justification for the proposal. The PRC Manager will consult with a PRC Chair to determine if this recommendation should be presented to the full PRC committee. After receiving approval from the full committee, this recommendation will be proposed to the Cancer Center Clinical Research Executive Committee. Upon receiving approval from the Cancer Center Clinical Research Executive Committee, the proposed revision to the PRC’s function, policies, and procedures will be in effect.