GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

Georgia Cancer Center Policies

Protocol Review & Monitoring Committee Policy

Policy Statement

All cancer-related clinical research that occurs in the facilities that define the Georgia Cancer Center, with the exception of research studies involving healthy human subjects, the population sciences, and biomarker studies using anonymous samples, must be reviewed and approved by the Protocol Review & Monitoring Committee (PRMC) of the Georgia Cancer Center following the procedures described in this policy. No subjects may be enrolled in any clinical trial or protocol until the trial or protocol is approved by the PRMC and other specified institutional committees.

Reason For Policy

The PRMC review is part of a process to promote unified protocol implementation and translational research among investigators of various disciplines involved in cancer care. The PRMC review is designed to ensure the highest scientific quality for clinical research conducted at the Georgia Cancer Center, to prioritize studies with institutional objectives, and is in accordance with future National Cancer Institute (NCI)-designation guidelines.

Entities Affected By This Policy

All investigators conducting cancer-related clinical research in the facilities that define the Georgia Cancer Center, with the exception of research studies involving healthy human subjects, the population sciences, and biomarker studies using anonymous samples, must adhere to this policy. All Georgia Cancer Center faculty and staff involved with the preparation of protocol and grant applications affected by this policy must know the content and procedures contained within this policy.

Contacts

Contact	Phone	e-mail/URL
PRMC Office, Georgia Cancer Center	706-721-0730	prmc@augusta.edu
Chair, PRMC, Georgia Cancer Center	706-721-7141	prmc@augusta.edu

Definitions

These definitions apply to these terms as they are used in this policy:

NCI	National Cancer Institute
NCI-designated Cancer Center	A trans-disciplinary translational research center focused on scientific and medical concerns relevant to cancer, and recognized ("designated") as such, according to strict criteria, by the National Cancer Institute of the National Institutes of Health (NIH).
Georgia Cancer Center (GCC)	Composed of M. Bert Storey Cancer Research Building and Georgia Cancer Center Outpatient Clinic at Augusta University (AU).
PRMC	Protocol Review & Monitoring Committee of the Georgia Cancer Center.
IRB	Institutional Review Board. In the context of this policy, IRB will refer to the oncology-focused IRB (IRB-C) at AU or external IRBs utilized by AU.

Overview

The purpose of the Protocol Review and Monitoring Committee (PRMC) is to provide internal scientific review for all new cancer and cancer-related studies within the Georgia Cancer Center, as further described below. A major objective of this review is to prioritize studies to meet the institutional objectives of designation as a Comprehensive Cancer Center by the National Cancer Institute (NCI). The review will maximize scientific validity, assure rapid and effective performance, and assess utilization of shared resources, and thus ensure the highest scientific quality of clinical research conducted at the Georgia Cancer Center. The procedures described herein were developed in accordance with the NCI guidelines for protocol review and monitoring, as required for all NCI-designated cancer centers.

Functions of the PRMC:

- To review the scientific and operational progress of all new and active cancer-related, clinical research protocols.
- To review appropriateness of the trial design and statistical analysis plan.
- To prioritize competing studies and resources based on Georgia Cancer Center's institutional prioritization plan.
- To assess the feasibility of all studies (e.g., institutional resources, focus, patient population).

Authority

Authority for Georgia Cancer Center review of clinical cancer-related protocols, including initiation, monitoring and termination, has been delegated by the Georgia Cancer Center Director to reside with the PRMC. The PRMC Chair is appointed by the Georgia Cancer Center Director, as specified in this policy,

and the Chair appoints the members of the PRMC. The Chair will inform the Principal Investigator (PI) of all PRMC decisions, including any relevant comments, in writing. The Georgia Cancer Center Director will be informed of all approval and termination actions. Protocols will not begin subject accrual until approved by the PRMC, IRB, and other institutional entities, with final approval residing with the Director of the Georgia Cancer Center.

Scope

This policy applies to all cancer-related clinical research performed in the facilities of the institution(s) that define the Georgia Cancer Center. However, the PRMC will not evaluate or prioritize studies dealing with healthy human subjects and the population sciences (i.e., observational and epidemiologic studies). Biomarker studies using anonymous samples from the Georgia Cancer Center Biorepository ("Tumor Bank") will not be reviewed by the PRMC. A dedicated Tissue and Tumor Biorepository Review Committee (TTBRC) will review these protocols (see Appendix 10). The PRMC will execute the approval/disapproval process and provide the final decision letter.

The PRMC review should not duplicate traditional peer review, which includes peer-reviewed protocols supported by the various NIH mechanisms, other approved funding agencies, and clinical research protocols approved by NCI's Cancer Therapy Evaluation Program (CTEP) or the Cancer Control Protocol Review Committee. These protocols receive an expedited administrative review for the purpose of prioritization only.

Process/Procedures

1. General Process

The PRMC may elect to perform a 2-stage review in which institutional concepts, without a full protocol, are first reviewed for scientific merit. Review of the protocol itself will occur as the second stage.

Stage 1: Letter-of-Intent (LOI) submission. This optional pathway is a process to discuss the initial concept of investigator-initiated studies. The LOI will be fully evaluated by the review process.

Stage 2: Full-protocol submission. This is a requested application, possibly preceded by a LOI initial submission.

The protocol will be reviewed by the PRMC in two different categories:

- NIH-sponsored studies: administrative expedited review (see Section 8 below)
- Others: full board review

(Phase 1 and 2 studies may receive a fast-track review process, see Section 9 below).

Following recommendation by the PRMC, the protocol will be submitted to the Georgia Cancer Center Director for review and approval, at which point it will be submitted to the Institutional Review Board (IRB). After the protocol is approved by the IRB, it will be resubmitted to the Georgia Cancer Center Director for final approval, who will then notify the PI.

2. Process for submission: *new application*

Protocol registration into the OnCore system is required before submitting to the PRMC and/or IRB. Details of this process can be found in Appendix 2A. The investigator shall submit the following documents (with the assistance of the AU Clinical Trials Office) for review of any new protocol or LOI:

i. A completed prioritization or routing sheet will be submitted with all protocol or LOI submissions. Any submission NOT including a completed prioritization or routing sheet will be rejected by the PRMC office.

ii. All submitted protocols must be in final format. No draft protocols or pre-finalized versions will be accepted. LOI submissions will use the CTEP template.

iii. The PRMC submission packet will include the following (as a PDF packet):
   - Initial PRMC Submission Form (see Appendix 2B)
   - Completed Prioritization or Routing Sheet (see Appendix 3)
   - Letter of Support from Disease-Oriented Working Group (DOWG) Leader (see Appendix 5) or Department Advocacy Letter if no DOWG Leader exists (see Section iv below) The DOWG letter of support should identify the following:
     - List of any and all competing ongoing clinical trials.
     - Confirmation that no directly competing trials will be developed during the duration of the submitted trial.
     - Confirmation of support for accrual to the trial.

iv. Protocols submitted to the PRMC must document past experience in the disease and identify expected accrual for the new trial. Discrepancies in past experience and projected accrual must be covered in a letter to the PRMC.

All new Georgia Cancer Center investigator-initiated studies should follow the AU Master Protocol Format or the CTEP LOI format.

These documents must be received by the circulated deadline dates in order to be reviewed at the next scheduled PRMC meeting. Deadlines vary depending upon whether Clinical Trials Office assistance with document preparation is requested.

3. Review Process

The review process is designed to ensure the highest quality of research according to the following criteria:

- High scientific merit, including rationale, study design, and adequacy of biostatistical input.
- Clinical feasibility.
- Reasonable accrual for completion within a practical time frame.
- Benefit to our patient population.
- Availability of funding.

Once a protocol is submitted to the PRMC, the protocol/LOI and routing sheet will be circulated for review by all attending members of the Committee. A

Primary, Secondary, Biostatistician and Pharmacy Reviewer will be assigned by the PRMC Chair for each protocol. All Reviewers will complete and sign the Protocol Review Worksheet (see Appendix 6). This worksheet requires an evaluation of both Scientific Merit (Part I) and Prioritization (Part II) using the following criteria:

i. Scientific rationale
ii. Study design
iii. Primary/secondary end points
iv. Inclusion/exclusion criteria
v. Adequacy of biostatistical input
vi. Feasibility for completion within a reasonable time period
vii. Scientific impact
viii. Competing trials
ix. Inclusion of translational research
x. Provision of care that does not currently exist at AU
xi. Enhance referral of patients and reputation of the Georgia Cancer Center and the PI
xii. Expected accrual rates
xiii. Enhance relationship with sponsor
xiv. Match with the institutional scientific mission.

Informed consent documents will NOT be reviewed by the PRMC. The PRMC will oversee the prioritization of competing protocols for use of Georgia Cancer Center resources (e.g., personnel and patients) from all sources, including cooperative group trials and industry trials, thereby ensuring optimal use of clinical resources for scientific purposes.

The PI may attend the meeting to answer questions about the study but should be out of the room during the entire presentation, discussion, and vote. This applies also if the investigator is a member of the Committee.

Protocols will be scored for both Scientific Merit and Prioritization based on the Protocol Review Worksheet (see Appendix 6). The scores for Scientific Merit will be totaled, with 12 being the best possible score, and 5 being the worst possible score. A protocol receiving a score of 1 for any of the Scientific Merit categories/criteria will not be approved. Therefore, the total score must be at least 8 points for the protocol to receive approval. Once Scientific Merit scores are tallied, the proposal will be voted upon by the Committee. [Note: A quorum for the meeting will consist of 50% of PRMC members; for further details of committee membership and meetings, see Section 6 below]. The outcome for Scientific Merit will be determined by majority decision of eligible voters. The protocol will then be reviewed for Prioritization. Protocols will be rated as high or low priority based on the score, general discussion and vote by the Committee as described above for Scientific Merit.

Thus, there are five possible recommendations for a protocol after PRMC review:

- Approval with high priority score
- Approval with low priority score
- Conditionally Approved
- Table
- Disapproval

The recommendations of the PRMC regarding both Scientific Merit and Prioritization will be submitted to the Director of the Georgia Cancer Center, who will make the final determination of approval/disapproval.

Each investigator will be notified of the outcome of his/her protocol review, along with relevant comments and required actions, within a reasonable time frame, typically within 3 working days of the review meeting, in order to allow for corrections to be made prior to the IRB deadline. Specific criticisms or questions will be detailed in the written report forwarded to the investigator.

4. Outcomes: Recommendations of Approval/Disapproval

Approval:

- The protocol is fully approved. The document(s) will then be forwarded to the Georgia Cancer Center Director for approval and then the IRB for its review. Patient accrual may begin once all other appropriate regulatory approvals are obtained (e.g., IRB, other institutional committees, FDA).
- The LOI is fully approved. The full protocol can be submitted to the PRMC.

Conditionally Approved:

The protocol/LOI requires minor clarifications or a response to concerns, but does not need to be re-reviewed by the full committee. The Chair or designee may approve the response, or may request that the committee review the response at the next meeting.

Table:

The protocol/LOI requires significant modifications and/or the PRMC has significant concerns. The investigator must make the required modifications, and submit the revisions and/or a response. The response will be reviewed at the next committee meeting, and the committee will again vote on the appropriate action.

It is assumed that studies submitted to the PRMC will meet the minimum requirement for patient safety, confidentiality, etc. as set out by the AU oncology-focused IRB (IRB-C). Studies will be tabled if these rules are not met; however, those guidelines will not be reiterated here.

Studies will be tabled by the PRMC for the following reasons:

- The investigator must provide information in the "Background" section of the protocol to justify the conduct of the trial. If the Committee determines that this information is incomplete or that there is insufficient preclinical or

clinical data to warrant conduct of the study being proposed, the protocol will be tabled until this material is provided.

- The protocol/LOI as proposed must be written such that it will meet the study objectives as determined by the investigator. If it is ascertained by the Committee that completion of the study will not result in an answer to the questions being asked, the study will be tabled. This could be due to inadequate biostatistical design, faulty study design, or an improper/inadequate data collection design.
- Studies will be tabled if it is felt by the Committee that the investigator does not have access to an adequate patient population to complete the trial in a reasonable time period. In general, this will require that the investigator be an active participant in the multidisciplinary clinic for the disease to be studied, or submit a letter from the director(s) of the clinic assuring their active participation. If a protocol proposes to enroll a similar or identical population of patients as a study that is already approved and open, the investigator must justify this in writing to the Committee.
- It is part of the mission of the Committee to ensure that a limited resource is used to its maximum potential and is available to all members of the Georgia Cancer Center. If it is felt by the Committee that a proposed protocol will consume an inordinate amount of resources either in terms of money or personnel, the study will be tabled. The investigator will then be asked to justify the use of these resources or resubmit the study after funds to pay for these resources have been obtained.
- An exception to this will be studies that are being submitted for funding to agencies that require PRMC/IRB approval prior to consideration. In this instance, studies will be approved but not opened until funding has been secured by the investigator and reviewed by the AU Clinical Trials Office.

Disapproval:
Specific reasoning for disapproval will be provided to the PI via written communication. A disapproved protocol/LOI will not be eligible for usage of shared resources.

5. Annual Review:

Studies that have been approved for enrollment will be reviewed annually, or more frequently, at the discretion of the PRMC for accrual, changes in scientific merit, protocol compliance and changes in prioritization since the last PRMC review.

Annual reviews for all protocols will be conducted by the PRMC. By a majority vote, the protocol will either be re-approved for one year, 3-6 months, or terminated. In the same manner as stated for new protocol reviews, a letter will be forwarded to the investigator stating any questions or criticisms concerning the ongoing progress of the study.

Conditions taken into consideration for annual review include:

- Accrual goal met vs insufficient accrual rate (following adequate notice with PI).
- Emergence of new information that diminishes the scientific importance of the study question.

As outlined in the routing sheet, documentation of prior accrual in disease sites will be required at the time of PRMC submission. Accrual goals and past experience will be significant factors in the evaluation of the overall scientific value of clinical trials. Georgia Cancer Center-sponsored studies for which accrual based upon past experience is questionable will be required to incorporate a "sunset clause" in the statistical section that will be based upon projections from the PI. Any study not attaining pre-set accrual goals will be closed as per the protocol.

Clinical trials (excluding cooperative group studies) that are expected to accrue low numbers of patients ($\leq$10/year) will be assessed critically for overall scientific value and feasibility of accrual. It should be recognized that in instances where an overriding reason for approval does not exist, disapproval of such studies will be considered. Such studies, if approved, will be subject to evaluation of accrual at the time of their annual review.

Conflicts regarding PRMC decisions will be arbitrated by the PRMC Chair or his/her designee.

6. Membership of the PRMC

Chairperson:

The Chairperson of the PRMC will be appointed by the Director of the Georgia Cancer Center to serve for a term of two years, with no limit to the number of term renewals.

The Chairperson of the PRMC will provide leadership and direction for the scientific review of cancer and cancer-related trials and in this capacity may also provide:

- Input to the Georgia Cancer Center Director regarding the conduct of cancer clinical trials.
- Review of Quality Assurance/Quality Control reports and provide recommendations.

Scientific Administrator:

The Scientific Administrator (SA) will be appointed by the Director of the Georgia Cancer Center to serve for a term of two years, with no limit to the number of term renewals. The SA is a non-voting member of the committee, but may be appointed by the Chair as a voting member *pro tempore*. The SA will take minutes of PRMC meetings and forward them to the Chair for approval and will perform other functions as requested by the Chair.

Membership Qualifications:

The Chairperson of the PRMC will appoint members to the PRMC from all relevant programs at AU. These persons should have an interest in and be

knowledgeable in protocol development and the conduct of clinical trials. Membership on the Committee will incorporate Georgia Cancer Center members from a variety of disciplines with assignment of members based upon prior utilization and proposed research volume.

When fully staffed, the goal of representation of the PRMC should include:

- Adult Hematology/Oncology 3-5 members
- Pediatric Hematology/Oncology 1 member
- Surgical Oncology Services 3-5 members
- Radiation Oncology 1 member
- Radiology 1 member
- Pathology 1 member
- Biostatistics 2 members
- Investigational Drug Pharmacist 1 member/1 alternate(1 vote)
- Basic Science 4 members
- Prevention/Population-based Science 1 member
- Cancer Center Research Nurse 1 member (non-voting)
- Oncology Trainee 1 member
- *Ad Hoc* Members (non-voting) 5 members

Ad Hoc non-voting members represent those members of the Georgia Cancer Center with a specific area of expertise who will be invited to meetings to review sub-specialized protocols in their discipline. These members will review protocol documents and provide input for consideration by the voting members. The number of non-voting members may be limited at the discretion of the Chair. The Administrative Coordinator and Scientific Administrator will be standing non-voting members appointed by the Chair. The Scientific Administrator can be appointed as a temporary voting member of the committee at the discretion of the PRMC Chair.

If a PRMC member is unable to attend a meeting, he/she will inform their alternate to attend the meeting in their place.

Ex-officio Members

The Director of the Georgia Cancer Center, the PMRC Chair and the PRMC Vice Chair (who is appointed by the Chair) will serve as *ex-officio* members.

Length of Term

The term of office for all voting members of the PRMC, as well as the Chair, shall consist of two years. There is no limitation to the number of terms one may serve. Appointments and reappointments will be performed by the PRMC Chair.

7. Coordination

The Georgia Cancer Center will ensure that adequate staff support is provided to the PRMC. The Committee will be served by an Administrative Coordinator. Protocols will be assigned for review by the Chair and distributed for review by the Administrative Coordinator.

Minutes of the meeting will be taken by the Scientific Administrator and forwarded to the Chair and the Administrative Coordinator. The PRMC Chair will inform the individual investigator of the Committee's decision, in writing, regarding a submitted protocol, including any relevant comments. All correspondence related to PRMC protocol review will be maintained by the Administrative Coordinator. The Georgia Cancer Center Director will receive a list of all reviewed protocols including the Committee's decisions.

The following membership letters will be sent by the Scientific Administrator, on behalf of the Georgia Cancer Center Director.

- Appointment letters for new members.
- Thank-you letters for departing members, to thank them for their service and acknowledge their PRMC membership termination.

8. Administrative Expedited Review

A protocol is eligible for expedited review if it meets one of the following criteria:

- Studies approved by the NCI Cancer Therapy Evaluation Program (CTEP) or Cancer Prevention and Control Protocol Review Committee, supported by an NIH funding mechanism (e.g., R01, U01, U10, P01), which requires full peer review as part of the funding process.
- Cooperative group studies, which have been reviewed extensively by NCI and various other national groups.

The PRMC Chair (or designee) will assign 3 reviewers (primary, secondary, and pharmacy) to the protocol and will make the recommendation with particular attention to prioritization based on the reviewers' recommendation. Expedited reviews will be completed as they are received, with a goal of completion of the review within 10 working days.

The possible actions during expedited review are the same as for full review.

The protocol may be re-assigned to the full review path at the discretion of the PRMC Chair, if he/she feels that full review is warranted. The PI will be informed of the PRMC's decision in writing.

Protocols that are approved via the expedited pathway will be added to the agenda and minutes of the next full PRMC meeting.

9. Fast-track Review

Early Phase Clinical Trials or other outstanding protocols may be reviewed following a fast-track process, if needed. The PI will contact the PRMC Chair and will provide relevant reasons for solicitation of this review. The PRMC Chair has the sole authority to authorize a fast-track review.

Fast-track review will ease the PRMC's review process for these nationally or internationally competitive studies and will allow the Committee to review these types of studies in an expedited fashion. These reviews will be completed as they are received, with a goal of completion of the review within 10 working days. The approval or need for full review will be reported at the next meeting.

10. Relationship of PRMC with Institutional Review Board

The Protocol Review and Monitoring Committee functions independently of the Institutional Review Board, and is considered to have a distinct role. The primary charge of the IRB is that of human subject safety, while the primary role of the PRMC is to maximize the scientific quality of research and the utilization of shared resources. Protocol Review Notification Letters, along with the study-specific PRMC minutes, are forwarded to the IRB per their request.

11. Miscellaneous Procedural Issues

Materials for review will be circulated to members one week prior to the meeting date. The PRMC will meet twice a month (first and third Wednesdays of the month). A listing of PRMC submission deadlines and meeting dates will be circulated on an annual basis. Minutes of each Committee meeting will be circulated to all members.

12. Revision of Guidelines

The guidelines of the Protocol Review and Monitoring Committee may be changed or revised with approval of the PRMC Chair. See Addendum for Revision History.

Administrative Addendum to PRMC Policy

Determination of Number of Members Required for Quorum

Effective Date: 1 February 2019

Sections of policy affected:

- Section 3. Review Process (paragraph 5)
- Section 6: Membership of the PRMC

Reason for Administrative Addendum:
In recent months (mid to late 2018), attendance at regularly scheduled PRMC meetings has waned, in part due to the heavy clinical loads of Georgia Cancer Center faculty as well as the required recusals when PRMC members are either the PI or a sub-investigator on the study. As a result, the Committee has had difficulty moving protocols through the process, due to the lack of a quorum. *It is a priority of the PRMC to process protocols in a timely way so there are no delays in moving protocols through the Institutional Review Board, obtaining final approvals, and ultimately opening studies and enrolling patients.* Currently the PRMC consists of 16 members, with 8 members (50%) constituting a quorum.

Modification of Policy:
Based on the above information and as suggested by the Interim PRMC Chair (David Munn, MD), in concordance with the Scientific Administrator (Rhea-Beth Markowitz, PhD) and the Coordinator (E. Katie Reeves), **the number of members required for quorum has been temporarily decreased to 6 (37.5%), with the provision that at least one Biostatistician and one Investigational Drug Pharmacist is present and counted in the quorum.**

This Administrative Addendum can be rescinded as the number of Clinical Faculty of the Georgia Cancer Center achieves full strength and the PRMC is fully staffed, as described in Section 6 of the PRMC Policy.

Addendum approved by Dr. David Munn, Interim PRMC Chair
Date of approval: 30 January 2019

Addendum

Revision History

Date	Description	Revised by/Approval by
7/1/2012	Originally issued	RBM/OR
10/16/2012, 11/19/2012	Minor changes per PRMC; became final version	RBM/OR
10/23/2013 11/22/2013	To reflect name change to Georgia Regents University; administrative change, membership section	RBM/OR
4/21/2014	To include TTBRC policy as Appendix	RBM/OR
7/13/2015	Update Appendix forms; addition of Scientific Administrator and define duties of the role	XX/RBM/DM
7/15/2016	To reflect name change to Georgia Cancer Center at Augusta University (partially done); update forms	CM/DM
4/3/2017	To reflect name change to Georgia Cancer Center at Augusta University; add Addendum: Revision History; procedural updates; formatting changes	RBM, CM/DM
4/27/2018	To change PRMC website address/OnCore submission address; change PRMC coordinator information for new coordinator; add Annual Review routing sheet and Expedited and Annual Review reviewer worksheets. Other minor administrative changes, including composition of PRMC.	RBM/EKR/DM
1/31/2019	Added Administrative Addendum to PRMC Policy for Determination of Number of Members Required for Quorum (Page 12 – Effective Date 2/1/2019); Minor administrative changes.	RBM/EKR/DM

RBM: Rhea-Beth Markowitz, PhD, Scientific Administrator
OR: Olivier Rixe, MD, PRMC Chair (founding)
XX: Xiayang (Chloe) Xie, PRMC Coordinator
CM: Carrie McAteer, Interim PRMC Coordinator
DM: David Munn, MD, Interim PRMC Chair
EKR: Eleanor (Katie) Reeves, PRMC Coordinator

Appendices

1. Georgia Cancer Center PRMC Statement of Process (SOP)
2. Submission of New Protocol for PRMC Review: Instructions: 2A; Form: 2B
3. PRMC Routing Sheet for Full Review
4. PRMC Routing Sheet for Expedited Studies
5. PRMC Routing Sheet for Annual Review
6. Disease-Oriented Working Group (DOWG) Leader(s) Support Letter
7. PRMC Review Worksheet (Full Review)
8. PRMC Review Worksheet (Full Review) Biostatistics
9. PRMC Review Worksheet (Expedited Review)
10. PRMC Review Worksheet (Annual Review)
11. Letter of Intent template
12. PRMC Meeting Agenda Form
13. Composition and Mandate of the Tissue and Tumor Biorepository Review Committee (TTBRC)

Appendix 1: Georgia Cancer Center Protocol Review and Monitoring Committee: Statement of Process (SOP)

The Protocol Review and Monitoring Committee will meet the first and third Wednesdays of every month to review new and tabled research studies. The Committee will decide if the science is viable and of interest to the Georgia Cancer Center and Augusta University. New studies will be submitted to the Clinical Trials Office via OnCore. The PRMC Chair will select five studies to be reviewed at each meeting by the Committee. The Chair will assign reviewers to perform individual reviews of the desired study. The assigned reviewers will read over the informational packets that are developed by the PRMC Office. The reviewers will make note of the rationale, feasibility, scientific merit, and analytical plan of the study. Once their reviews are complete, the reviewers will forward their comments and recommendations to the PRMC Office on a Protocol Review Worksheet (see Appendices 6 & 7) provided in the packet. The Committee will meet to review and discuss each reviewer's comments. A vote will be taken to recommend if the study should be approved, conditionally approved, tabled, or disapproved. If the recommendation is approval, the study moves forward to the Georgia Cancer Center Director for approval, and then the IRB process. If the recommendation is conditional approval, the response must be reviewed and approved by the Chair before submission to the Director and IRB. If tabled, the study will go through another PRMC approval meeting process upon resolution of deficiencies. The PRMC will perform annual reviews of research studies to review accrual and continued scientific merit. The following process supports the activity of the PRMC.

1. The PI/designee completes the "PRMC Protocol Submission" form available on the OnCore website (http://www.augusta.edu/research/cts/oncore/forms-sops.php), including uploading the following study-related documents:
   A. Completed Initial PRMC Submission Form (Appendix 2B)
   B. Completed PI Routing Sheet (Appendices 3 or 4)
      i. A complete, signed routing sheet must be included for all protocols. Any submission NOT including a completed routing sheet will NOT be reviewed by the PRMC.
      ii. Note that there is a different routing sheet to use for Cooperative Studies.
   C. Supportive Letter from Disease-Oriented Working Group (DOWG) Leader (Appendix 5) or Department Advocacy Letter, in the absence of a specific DOWG Leader)
   D. Protocol and Appendices - All submitted protocols must be in final format. No draft protocols or pre-finalized versions will be accepted. Informed consent documents will NOT be reviewed by the PRMC.
   E. Investigator Brochure, if applicable
2. Up to five protocols will be selected for the next meeting's agenda. The Chair includes old business and new business issues as needed. Additionally, the PRMC office schedules studies that are due for annual review.

3. The PRMC Office creates an agenda (Appendix 9) that includes the study title, names of the Principal Investigator and Sub-Investigators, Primary Reviewer, Secondary Reviewer, and Biostatistics and Pharmacy reviewers. Administrative staff fills in the Study Title, PI and Sub-I information then forwards the agenda to the PRMC Chair for Reviewer assignments.

The PRMC Office uses the Review Worksheet Template to create a Review Worksheet specific to each study on the PRMC Agenda. Each review worksheet is saved to the PRMC folder in the Augusta University Box.com platform. The PRMC Office creates a PDF packet for each study and saves it to Box.com.

A PRMC Committee e-mail is created by the PRMC Office distributing and clarifying the agenda for the upcoming meeting. All information must be distributed to committee members at least one week prior to the meeting. The e-mail template is updated to contain the current month's agenda.

The PRMC Office assists with preparation for the meeting as needed.
Review worksheets signed by reviewers are collected during, prior to, or just after the meeting.

i. The PRMC meeting is documented by taking notes, and using the reviewer worksheet scores and comments. Meeting minutes are generated by the Scientific Administrator and approved by the PRMC Chair, then saved to Box.com under PRMC Packets, meeting date-specific.
ii. The review worksheets are scanned and saved to Box.com under PRMC Packets, study-specific.
iii. Letters are sent to each Principal Investigator stating the study was approved, conditionally approved, tabled or disapproved. The letters are sent via OnCore.
iv. Membership designation: The PRMC is multi-disciplinary with representation from all departments and divisions involved in cancer-related clinical and translational research. Members are contacted by letter and asked to participate as a member. Full members of the PRMC will be responsible to attend all meetings of the committee, to serve as the primary or secondary reviewer on selected studies, and review all studies in order to actively participate in discussions. Members are asked to designate an alternate member to serve in their absence. In the event a member cannot attend a meeting, it will be their responsibility to have their designated alternate execute these functions on their behalf. Members will be appointed for a two-year term.

    The Protocol Review and Monitoring Committee will consist of a Chair, Vice Chair, Scientific Administrator, Administrative Coordinator and representatives from each division/department.

    The PRMC is responsible for review of all new cancer-related studies that involve patients or patient samples conducted by members of the Georgia Cancer Center. This review is essential to ensure the highest quality of clinical research. An effective PRMC is an essential element of our Designated

Cancer Center application to the National Cancer Institute.

Meetings will take place on the first and third Wednesdays of each month at 12 noon. Meetings will last approximately 1-1.5 hours. A notification will be sent prior to each meeting with the location.

i. The PRMC Office makes Committee Member selections on recommendation of the Director or Department Chairs and solicitation from the PRMC Office to fill a specific Department or Division vacancy.
ii. The selected faculty/staff member will be invited to attend by letter. The Scientific Administrator will generate and coordinate signatures needed for an invitation letter. The letter will be signed by the Director of the Georgia Cancer Center and mailed to the prospective member.
iii. The faculty/staff member will respond via e-mail to the PRMC Chair with intent to serve and indicate possible alternate choice(s). The PRMC Chair will notify the administrative staff.
iv. The Scientific Administrator will create an Alternate(s) Invitation letter and coordinate the appropriate signatures. The letter should be signed by the Director of the Georgia Cancer Center and mailed to the prospective alternate.
v. The faculty/staff member will respond via e-mail to the PRMC Chair with intent to serve as an alternate. The PRMC Chair will notify the administrative staff.
vi. The PRMC Office will maintain an updated PRMC Membership list on the PRMC Web site.

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Protocol Submission Instructions to Georgia Cancer Center PRMC (New Applications)

All cancer-related clinical research protocols must be reviewed by the GA Cancer Center Protocol Review and Monitoring Committee (PRMC) prior to submission to the Institutional Review Board (IRB). Subject enrollment cannot begin until both PRMC and IRB approvals have been obtained and a Study Activation Notice has been received for that protocol.

PRMC Submission Requirements:

A. Completed Initial PRMC Submission Form
B. Completed Routing Sheet
   i. A complete, signed routing sheet must be included for all protocols. Any submission NOT including a completed routing sheet will NOT be reviewed by the PRMC.
   ii. Note that there is a different routing sheet to use for Cooperative Studies.
C. Supportive Letter from Disease-Oriented Working Group (DOWG) Leader (or Department Advocacy Letter, in the absence of a specific DOWG Leader)
D. Protocol and Appendices
E. Investigator Brochure, if applicable

All submitted protocols must be in final format. No draft protocols or pre-finalized versions will be accepted. Informed consent documents will NOT be reviewed by the PRMC.
All documents must be received by the circulated deadline dates in order to be reviewed at the next scheduled PRMC meeting. Deadlines may vary depending upon whether PRMC Office assistance with document preparation is requested.

How to Submit:

With the institution-wide implementation of the On-line Collaborative Research Environment (OnCore), **protocol registration in OnCore is required before submitting to PRMC and/or IRB**.

To request protocol registration, please visit the OnCore Online Forms web page at https://www.augusta.edu/research/tools-for-researchers/index.php and click on the "**OnCore – PRMC Protocol Submission**" link. Complete the online form and upload all required submission documents, as listed above. After you submit the online form, you will be contacted by the OnCore staff when your protocol has been registered and is ready for PRMC review.

PLEASE NOTE: The OnCore registration email will include instructions for submitting the protocol to the PRMC via the ePRMS Submission Console. **If you do not click "Send" in the ePRMS Submission Console, it will not show up on the PRMC Meeting Agenda.**

For questions about your submission, please contact the PRMC coordinator at PRMC@augusta.edu.

GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

Submission of a New Protocol for PRMC Review

Part A: Basic Information

Before completing this form, please review the Submission Instructions on the PRMC website: https://www.augusta.edu/cancer/research/grant-support-services/toolbox/prmc/submit.php. If you have any questions on how to fill out this form or questions related to this process, please call (706) 721-0730 or email prmc@augusta.edu.

Protocol Information

All submitted protocols must be in final format. No draft protocols or pre-finalized versions will be accepted.

Study Title:

PI:

Study Type: ☐Therapeutic ☐ Non-therapeutic

Type of Sponsor: ☐Investigator-Initiated ☐Pharmaceutical

☐Cooperative Group/NCI ☐Outside Institution

Sponsor Name: _____

Will this trial be conducted at Georgia Cancer Center/AU Health Center? ☐ Yes ☐ No

Will this trial be conducted at multiple sites within AU Health Center? ☐Yes ☐No

Please specify sites: _____

Will this trial be conducted at multiple sites nationally or internationally? ☐Yes ☐No

Please specify number of sites: _____

Does the Study require a local IND application? ☐Yes* ☐No

*If yes, please specify who will be the IND holder?_____

Disease Group Leader(s) Sign-Off

All cancer-related protocols must be reviewed by the applicable Georgia Cancer Center Disease-Oriented Working Group (DOWG) Leader(s) and competing studies and priority issues adequately discussed. ***Please Note****: For PRMC submission packet, you will be required to attach a Support Letter from a DOWG Leader (see Appendix 5).*

Check each DOWG that applies:

- ☐ Gynecologic Oncology (Gyn Onc) ~ *Sharad Ghamande, MD*
- ☐ Hematology-Oncology & Bone Marrow Transplantation (Heme/BMT) ~ *Jeremy Pantin, MD*
- ☐ Pediatric Oncology (Ped Onc) ~ *Colleen McDonough, MD*
- ☐ Phase 1/ Immunotherapy ~ *John Janik, MD*
- ☐ Radiation Oncology (Rad Onc) ~ *James Rawson, MD*
- ☐ Solid Tumor ~ *Shou-Ching Tang, MD*

Does this study compete with any current/future Georgia Cancer Center studies in this specific disease area? ☐Yes ☐No

Please list all competing trials and prioritize below (more can be listed on a separate sheet):

Protocol #: _____ ☐ Highest (1st) ☐ High (2nd) ☐ Priority Other:

Protocol #: _____ ☐ Highest (1st) ☐ High (2nd) ☐ Priority Other:

Part B: Requirement Checklist

Please Note: *The protocol will not be put on the PRMC meeting agenda until the PRMC receives a completed submission packet, which will include the following:*

- ☐ This Completed Submission form
- ☐ Completed Routing Sheet
  Note: there are two types of Routing Sheet depending on the type of sponsor.
  - *"Routing Sheet for Full Review" is for Pharmaceutical or investigator-initiated studies.*
  - *"Routing Sheet for Expedited Review" is for Cooperative Group studies.*
- ☐ DOWG Support Letter(s)
- ☒ Protocol, Appendices, and Investigator Brochure, if applicable

GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

Routing Sheet – PRMC Full Review (not Cooperative Studies)

Study Title:

Principal Investigator:

Phase: NA / I / II / III / IV

Study Coordinator(s):

Sub-Investigators:

Gene Therapy Study: Yes / No

Chart Review/Biospecimen Study: Yes / No

Study Funded: Yes / No **Source:**

Length of Accrual Period: _____ **years**
Total Study Accrual Goal: _____ **(all sites)**
Local patient population meeting criteria: _____ **(per year)**
Estimated local patient accrual per year: _____ **(per year)**

IND Status (if applicable): _____
Holder: _____
Applicant: _____

Study Drug(s): _____
Mechanism of action: _____
What is the hypothesis being tested? _____

Prioritization

The PI should score this section as described in each category below. Protocols that are approved for Scientific Merit will be rated as **high** or **low** priority based on the Prioritization score and general discussion from the committee.

Category/Criteria	Score
Does the study compete with PI-initiated studies? YES NO	
The study includes Institutional Translational Research. YES=1, NO=0	
The study provides care that does not exist at the Institution. YES=1, NO=0	
The study enhances referrals of patients. YES=1, NO=0	
Patient accrual: Expected total number of patients enrolled per trial: Score 3 = at least 2 patients in Phase I or Phase II trial Score 3 = more than 20 patients in Phase III trial Score 2 = 5 to 19 patients in Phase III or Phase IV trial Score 1 = less than 5 patients in Phase III or Phase IV trial	
Cancer Center Scientific Mission: (Please check one or more; and Score 0, 1, 2, 3 as noted below) ☐ Cancer Immunology/Immunotherapy, Tolerance, Inflammation ☐ Molecular Oncology and Biomarkers ☐ Signaling and Angiogenesis ☐ Cancer Prevention and Control Score 1 = the study involves at least one of these areas Score 2 = there is potential for collaboration or development of additional research studies from the trial (**Name of Collaborator:** _____**; Nature of Collaboration:** _____) Score 3 = the study specifically uses a product or strategy that is an existing strength at our institution Score 3 = there is a defined collaboration or additional research from the trial already included in the proposal	
The study enhances the reputation of the Georgia Cancer Center. YES=1, NO=0	
The study enhances the reputation of the PI. a. Publication YES=1, NO=0 b. Grant application YES=1, NO=0	
The study enhances the PI's and/or Institution's relationship with the sponsor. YES=1, NO=0	
Total Score	**/13**

Please provide a justification to open the study at Georgia Cancer Center/AU (e.g., reason to open, programmatic strategy, good use of available time and monetary resources).

Additional Comments:

PI Signature:_____ **Date:** _____

GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

Routing Sheet – PRMC Expedited Review (Cooperative Studies)

Study Title:

Principal Investigator:

Is this an NCORP study for administrative expedited review ONLY (No patients enrolled at GCC/AU)?
☐ **Yes** ☐ **No**
If yes, please stop here.

For Cooperative studies that will enroll at Georgia Cancer Center, please fill out the following information:

Phase: NA / I / II / III / IV

Local PI: _____

Sub-Investigators: _____

Study Coordinator: _____

Length of Accrual Period: _____ **years**

Total Study Accrual Goal: _____ **(all sites)**

Local patient pop. meeting criteria: _____ **(per year)**

Estimated local patient accrual: **(per year)**

Prioritization

The PI should score this section as described in each category below. Protocols will be rated as **high** or **low** priority based on the Prioritization score and general discussion from the committee.

Category/Criteria	Score
The study enhances the reputation of the Georgia Cancer Center. YES=1, NO=0	
The study provides care that does not exist at the Institution. YES=1, NO=0	
The study enhances referrals of patients. YES=1, NO=0	
The study contributes to Georgia Cancer Center NCORP (NCI Community Oncology Research Program). YES=1, NO=0	
Patient accrual: Expected total number of patients enrolled per trial: Score 3 = at least 2 patients in Phase I or Phase II trial Score 3 = more than 20 patients in Phase III trial Score 2 = 5 to 19 patients in Phase III or Phase IV trial Score 1 = less than 5 patients in Phase III or Phase IV trial	
The study provides the only way to access the investigational drugs/ agents. YES=1, NO=0	
Total Score	**/ 8**

Please provide a justification to open the study at Georgia Cancer Center/AU (e.g., reason to open, programmatic strategy, good use of available time and monetary resources).

Additional Comments:

PI Signature: _____ **Date:** _____

Annual Review Routing Sheet

GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

Routing Sheet – PRMC Annual Review

Study Title:	
Principal Investigator:	
Sponsor:	☐ **Pharmaceutical** ☐ **Investigator-Sponsored Trial (IST)** ☐ **Cooperative/ NCI**
Name of sponsor:	
Original PRMC Approval Date:	
Original IRB Approval Date:	
GCC/AU Site Initiation (Opening Date):	
Current Status of the Study: (please check one or more applicable boxes)	☐ **Open to accrual** ☐ **Closed to accrual (no patient(s) on the study)** ☐ **Closed to accrual (patient(s) on the study)** ☐ **Terminated**
Does this study currently compete with any PI – initiated studies?	☐ **Yes** ☐ **No**

ENROLLMENT	
Planned Subject Enrollment (from PRMC application):	
Local Subjects Screened Since Beginning of Study:	
Local Subjects Enrolled Since Beginning of Study:	
Local Subjects Screened in Past 12 Months:	
Local Subjects Enrolled in Past 12 Months:	

Please provide a short, two to three sentence overview of the study and the progress that has been made in the past year:

Please provide a justification to keep this study open at GCC/AU (e.g. programmatic strategy, good use of available time and monetary resources). **Additional Comments:**

PI Signature: _____ **Date:** _____

GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

March 21, 2017

David Munn, MD

Chair, Georgia Cancer Center

Protocol Review and Monitoring Committee

Re: Letter of support for study entitled: "Click here to enter text.**"**

Dear Dr. Munn:

I have reviewed the above referenced protocol. The present communication is to confirm that Dr. XXXX is granted permission to conduct the above referenced study at Augusta University.

In my role as Choose an item. Disease-Oriented Working Group Leader:
(Please mark one box)

☐ I confirm that there are no competing trials for this disease/indication.

☐ I am aware that the following competing trials are open in our group:

Study ID	Protocol Title	Disease/Indication	PI

This will be our group's plan for prioritizing patient enrollment for these trials: *(attach additional pages if needed)*
Click here to enter text.

I hereby confirm that the above is correct to my knowledge, and I assert my authority to grant this permission on behalf of our institution.

Sincerely yours,

Signature

Name

Title

GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

Full Review Worksheet
Primary/Secondary Reviewer

Name of Reviewer:	
Type of Reviewer:	☐ Primary ☐ Secondary

Please submit your review electronically (PRMC@augusta.edu) by 9 AM the morning of the PRMC meeting.

PRMC Study Number:

Study Title:

Principal Investigator:

Sponsor: ☐ Pharmaceutical ☐ Investigator-Initiated

Name of Sponsor:

Part I: SCIENTIFIC MERIT

The Primary & Secondary Reviewers should fill in any applicable comments or important information for each category/criteria. Score each category/criteria that is not shaded using the following scale:
3 = Outstanding; 2 = Acceptable; 1 = Not Acceptable. Provide a total score of all 4 categories with **12 being the best possible score**, and **4 being the worst possible score**. Any protocol receiving a score of **1 for any category/criteria may not be approved**. Therefore, the total score should be at least 8 points for the protocol to receive approval. *Biostatistics review will be done separately by the Biostatistician.*

Category/Criteria	Score
Scientific Rationale:	
Study Design: **Optional Comments:** *Primary Endpoints: *Secondary Endpoints: *Inclusion Criteria: *Exclusion Criteria:	
Adequacy of Biostatistics:	
Feasibility of completion within a reasonable time frame:	

Scientific Impact:	
Total Score	**/12**

Part II:	**PRIORITIZATION**

Score this section as described in each category below. Protocols that are approved for Scientific Merit will be rated as **high** or **low** priority based on the Prioritization score and general discussion from the committee.

Category/Criteria	Score
Does the study compete with PI-initiated studies? YES NO	
The study includes Institutional Translational Research. YES=1, NO=0	
The study provides care that does not exist at the Institution. YES=1, NO=0	
The study enhances referrals of patients. YES=1, NO=0	
Patient accrual: Expected total number of patients enrolled per trial: Score 3 = at least 2 patients in Phase I or Phase II trial Score 3 = more than 20 patients in Phase III trial Score 2 = 5 to 19 patients in Phase III or Phase IV trial Score 1 = less than 5 patients in Phase III or Phase IV trial	
Cancer Center Scientific Mission ***(Score = 0, 1, 2, 3, see below; Please check one or more)*** ☐ Cancer Immunology/Immunotherapy, Tolerance, Inflammation ☐ Molecular Oncology and Biomarkers ☐ Signaling and Angiogenesis ☐ Cancer Prevention and Control Score 1 = the study involves at least one of these areas Score 2 = there is potential for collaboration or development of additional research studies from the trial (**Name of Collaborator:** _____ **; Nature of Collaboration:** _____) Score 3 = there is a defined collaboration or additional research from the trial already included in the proposal Score 3 = the study specifically uses a product or strategy that is an existing strength at our institution	
The study enhances the reputation of the Georgia Cancer Center. YES=1, NO=0	
The study enhances the reputation of the PI. a. Publication YES=1, NO=0 b. Grant application YES=1, NO=0	
The study enhances the PI's and/or Institution's relationship with the sponsor. YES=1, NO=0	
Total Score	**/13**

Comments/Recommendations regarding advertisement/referral strategies:

Blinded Comments to PI:

Confidential Comments to PRMC:

Reviewer's Signature:

_____

Date of Review: Click here to enter a date.

Please check one to indicate your recommendation:
___ Approve with High Priority
___ Approve with Low Priority
___ Conditionally Approve
___ Table
___ Disapprove

GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

Full Review Worksheet
Biostatistician Reviewer

Name of Reviewer:	
Type of Reviewer:	☒ Biostatistician

Please submit your review electronically (PRMC@augusta.edu) by 9 AM the morning of the PRMC meeting.

PRMC Study Number:

Study Title:

Principal Investigator:

Sponsor: ☐ Pharmaceutical ☐ Investigator-Initiated

Name of Sponsor:

Part I:	**SCIENTIFIC MERIT**

The Biostatistician Reviewer should only fill in the category of "Adequacy of Biostatistics" that is not shaded using the following scale: **3 = Outstanding; 2 = Acceptable; 1 = Not Acceptable.**

Category/Criteria	Score
Scientific Rationale:	
Study Design:	
Adequacy of Biostatistics:	
Feasibility of completion within a reasonable time frame:	
Scientific Impact:	
Total Score	**/ 3**

Part II: Prioritization – Not applicable

*Protocols that are approved for Scientific Merit will be rated as **high** or **low** priority based on the Prioritization score and general discussion from the committee.*

Comments/Recommendations regarding advertisement/referral strategies:

Blinded Comments to PI:

Confidential Comments to PRMC:

Reviewer's Signature:

_____

Date of Review: Click here to enter a date.

Please check one to indicate your recommendation:
___ Approve with High Priority
___ Approve with Low Priority
___ Conditionally Approve
___ Table
___ Disapprove

GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

Expedited Review Worksheet
Primary/Secondary Reviewer

Name of Reviewer:	
Type of Reviewer:	☐ Primary ☐ Secondary

Please submit your review electronically (PRMC@augusta.edu) by 9 AM the morning of the PRMC meeting.

PRMC Study Number:

Study Title:

Principal Investigator:

Sponsor: NCI/Cooperative Groups

PRIORITIZATION	
Score this section as described in each category below. Protocols that are approved will be rated as **high** or **low** priority based on the Prioritization score and general discussion from the committee.	
Category/Criteria	**Score**
The study enhances the reputation of the Georgia Cancer Center. YES=1, NO=0	
The study provides care that does not exist at the Institution. YES=1, NO=0	
The study enhances referrals of patients. YES=1, NO=0	
The study contributes to the GCC NCORP (NCI Community Oncology Research Program). YES=1, NO=0	
Patient accrual: Expected total number of patients enrolled per trial: Score 3 = at least 2 patients in Phase I or Phase II trial Score 3 = more than 20 patients in Phase III trial Score 2 = 5 to 19 patients in Phase III or Phase IV trial Score 1 = less than 5 patients in Phase III or Phase IV trial	
The study provides the only way to access the investigational drug(s) / agent(s). YES=1, NO=0	
Total Score	**/ 8**

Comments/Recommendations regarding advertisement/referral strategies:

Blinded Comments to PI:

Confidential Comments to PRMC:

Reviewer's Signature:

_____

Date of Review: Click here to enter a date.

Please check one to indicate your recommendation:
___ Approve with High Priority
___ Approve with Low Priority
___ Conditionally Approve
___ Table
___ Disapprove

GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

Annual Review Worksheet

Name of Reviewer:	

Please submit your review electronically (PRMC@augusta.edu) by 9 AM the morning of the PRMC meeting.

PRMC Study Number:

Study Title:

Principal Investigator:

Sponsor: ☐ Pharmaceutical ☐ Investigator-Initiated

Name of Sponsor:

Original Priority Score: **Original Scientific Merit Score:**

Part I:	Prioritization for Continuation

Score this section as described in each category below.

Category/Criteria	Score
Does the study compete with PI-initiated studies? YES NO **If YES, give the name of the competing trial(s):** **Is the competing trial(s) investigator-initiated?** YES NO	
The study includes Institutional Translational Research. YES=1, NO=0	
The study provides care that does not exist at the Institution. YES=1, NO=0	
The study enhances referrals of patients. YES=1, NO=0	
Patient accrual: Expected total number of patients enrolled per trial: Score 3 = at least 2 patients in Phase I or Phase II trial Score 3 = more than 20 patients in Phase III trial Score 2 = 5 to 19 patients in Phase III or Phase IV trial Score 1 = less than 5 patients in Phase III or Phase IV trial	

Cancer Center Scientific Mission ***(Score = 0, 1, 2, 3, see below; Please check one or more)*** ☐ Cancer Immunology/Immunotherapy, Tolerance, Inflammation ☐ Molecular Oncology and Biomarkers ☐ Signaling and Angiogenesis ☐ Cancer Prevention and Control Score 1 = the study involves at least one of these areas Score 2 = there is potential for collaboration or development of additional research studies from the trial (**Name of Collaborator:** _____ **; Nature of Collaboration:** _____) Score 3 = there is a defined collaboration or additional research from the trial already included in the proposal Score 3 = the study specifically uses a product or strategy that is an existing strength at our institution	
The study enhances the reputation of the Georgia Cancer Center. YES=1, NO=0	
The study enhances the reputation of the PI. a. Publication YES=1, NO=0 b. Grant application YES=1, NO=0	
The study enhances the PI's and/or Institution's relationship with the sponsor. YES=1, NO=0	
Total Score	**/13**

Reviewer's evaluation and recommendation:

☐ Continuation ☐ Close Protocol ☐ Other (explain):

Reviewer's Signature:

_____

Date of Review: Click here to enter a date.

Appendix 11: Letter of Intent Template

Georgia Cancer Center:
LETTER OF INTENT

Lead/Group Institution:

Other organizations on study:

CTEP IND Agent:

Non-NCI IND Agent Supplier:

Commercial Agent(s) Source:

Tumor Type:

Disease-Specific:

Performance Status:

Abnormal Organ Function Permitted?

Prior Therapy:

Phase of Study:

Treatment Plan:

Rationale/Hypothesis:

Advanced Imaging Objectives:

Laboratory Correlates:

Endpoint/Statistical Considerations:

Estimated Monthly Accrual:

Proposed Sample Size:

Earliest date the study can begin:

Projected Accrual Dates:

To document accrual rate, list trials with patients who had similar Tumor Type/Phase of Study/Prior Therapy:

Protocol number
Trial activation
No. of Patients Enrolled:

List of Active, Approved or in Review studies at your institution for which this patient population will be eligible:

Protocol number/Title/Sponsor/
Trial Activation Date/Anticipated Completion Date/

No. of patients enrolled to date:
Duration of Patient Enrollment:
Total Planned Patient Enrollment:

Is this LOI part of an NIH Grant, Cooperative Agreement or Contract: Yes/ No
If Yes, Award number:
Will this study receive support from non-NCI sources?
If the proposed trial includes correlative studies, AU assumes funding is available to support them.
If yes, is it grant funding?
If yes, provide the grant number:

Principal Investigator name: _____

PI Signature: _____ Date: _____

PI contact Information: _____

Georgia Cancer Center Disease-Oriented Working Group Leader agreement:

Name: _____

Signature: _____ Date: _____

Appendix 12: Georgia Cancer Center PRMC Meeting Agenda

1. Introduction
2. Approval of minutes
3. Review of new protocols
4. Review of expedited protocols
5. Annual reviews
6. Previously tabled protocols
7. Announcement of administratively approved protocols
8. New business

Appendix 13: Composition and Mandate of the Tissue and Tumor Biorepository Review Committee

The Tissue and Tumor Biorepository Review Committee (TTBRC) functions in concert with the PRMC, and is considered to be an organ of the same. The primary charge of the TTBRC is to evaluate and prioritize protocols relating to the use of human tissues archived in the Tissue and Tumor Biorepository (TTB), while the primary role of the PRMC is to maximize the scientific quality of research and the utilization of shared resources. Actions emanating from the TTBRC are considered recommendations and subject to review and sanction by the entirety of the PRMC. Periodic review of the actions and activities of the TTBRC will be provided by the TTB External Advisory Committee.

A) The composition of the TTBRC (target membership = 9) shall include:

*	Adult Hematology/Oncology	1 – 2 member(s)
*	Surgical/Gynecology Oncology	2 – 3 members
*	Pathology	1 – 2 member(s)
*	Biostatistics	1 – 2 member(s)
*	Basic Science (Cancer Center)	3 – 5 members

B) Proposal submissions will be submitted to the TTBRC office using the TTBRC submission form available on the PRMC Web site. Proposals are anticipated to be of 2 scales:

1) Pilot study (<20 samples) – this will require a rigorous scientific rationale with high likelihood of success. To access TTB samples, there needs to be an explicit design that obviates the use of conventionally available samples. At minimum, there needs to be literature support for the rationale and, preferably, preliminary data that suggests a high likelihood of scientific impact. Statistical design should be included, but does not require explicit power analysis.

2) Full proposal – this will require an explicit dedicated funding source and should be linked to a major scientific proposal that has or shows high likelihood of intra- or extramural funding commitment. Sample requirements may be prospective or retrospective (or both), depending on the status of the tumor bank inventory. Collaborative projects and studies that generate additional resources available to the greater AU and scientific community will receive greatest priority.

C) Proposals will be routed (via the Tumor Bank Director, designated Chair of the TTBRC) to at least one primary and one secondary reviewer (including or in addition to biostatistician review). Proposals will be made available to all TTBRC members via email. Reviews are due within one week for pilot project review and 2 weeks for full proposal review and should be submitted to the Chair of the TTBRC

D) Reviews and primary recommendation shall be disseminated to the full TTBRC membership by the Chair. A formal vote for approval shall be compiled by the Chair. Majority rule ($\geq$ 5 votes in support or denial of the proposal) shall be considered TTBRC sanction. The subsequent recommendation to the PRMC shall constitute one of four options:

- Approve
- Disapprove
- Table
- PRMC Review Requested

E) Formal meetings shall be limited to twice annually. Electronic communications shall comprise the bulk of the interactions for the TTBRC. The composite electronic communications shall comprise the official minutes of the TTBRC.