I. ORGANIZATION:
The Scientific Research Committees (SRCs) are officially constituted committees of The University of Texas MD Anderson Cancer Center (MD Anderson). The SRC reports to the Vice President and Deputy Chief Academic Officer, Clinical and Interdisciplinary, through the Office of the Vice President for Clinical Research Administration.

II. PURPOSE:
The purpose of the SRC is to evaluate the scientific content of all research requiring a clinical protocol. A clinical protocol is a detailed plan of the scientific or medical experiment, treatment, device, or procedure. The SRC will review investigator-initiated trials (sponsored or non-sponsored), as well as protocols sponsored by pharmaceutical and biotechnology companies, whether they are single center or large multi-center trials. All clinical investigations involving human subjects will need to be approved by the Institutional Review Board (IRB) prior to activation. In this regard, the SRCs are the scientific reviewing agents for the IRB and are critical components of the Protocol Review and Monitoring System (PRMS) for MD Anderson’s NCI Core Grant.

III. RESPONSIBILITIES:
The SRCs have the responsibility for reviewing all aspects of the scientific research that are included in the protocol plan. The protocol plan includes specific aims, background and rationale, methods used to validate the scientific questions being asked, methods for the biostatistical analysis to establish the success or failure of an experiment, and the required radiologic and pathologic research evaluations, as well as pharmaceutical information provided in the protocol.

The Co-Chairpersons will be responsible for assigning the medical, content expert, and other multidisciplinary reviewers for the newly submitted protocols. Once the protocol is ready for the committee to review, the Co-Chairpersons will assign a primary discussant to summarize the reviews and present a suggested impact score for each protocol that will be presented at the upcoming SRC meeting unless it is a PI initiated protocol. If it is a PI initiated protocol, then primary and secondary discussants will be selected for review. The SRC Co-Chairpersons will rotate setting the meeting agendas with the assistance of the SRC Specialist from the Office of Protocol Review and Reporting. A Co-Chairperson can fill in to chair a meeting if the other Co-Chairperson has an unresolvable conflict or is unable to attend.

IV. MEMBERSHIP:
There are four different SRCs that meet once a month. Each committee will have two Co-Chairpersons who are senior clinical faculty at MD Anderson, and who will be appointed annually by the Vice President and Deputy Chief Academic Officer, Clinical and Interdisciplinary and the Vice President of Clinical Research Administration. There will be at least 15 members appointed to each of the SRCs with representation from the majority of the Institutional Divisions, including Surgery, Pediatrics, Pathology/Laboratory Medicine, Radiation Oncology, Cancer Prevention, Internal Medicine, and Cancer Medicine. Committees will also have multidisciplinary members from Diagnostic Imaging, Pharmacy, Nursing, Pathology and the Quantitative Sciences Division. SRC members are selected based upon their areas of expertise. Each member of the committee will score the reviewed protocols using defined criteria. In addition, each SRC will have one community member. This community member is a volunteer member to further strengthen our clinical research.

There should be a minimum of eight voting members present to constitute a quorum for a meeting. If need be, the quorum can be lowered to seven to begin the meeting. The committee members will be replaced if attendance is below acceptable limits. Below acceptable limits would be half the number of meetings within a fiscal year. The Vice President and Deputy Chief Academic Officer, Clinical and Interdisciplinary along with the Vice President of Clinical Research Administration will annually appoint SRC members at the appropriate time within the academic year and replace vacating members as needed. Membership will be reviewed on a quarterly basis, and members with low attendance will receive warning letters from the SRC Co-Chairs of that particular meeting. If attendance does not pick up, the committee member will be replaced.
V. MEETINGS:
The SRC meeting has an open and closed session, but is only open to guests and presenters upon invitation. All committee meetings start at 1:00 pm and convene on various days of the week within the month. The months in which there are a fifth week, each SRC Committee will take on an extra meeting per fiscal year. These meetings will be labeled as Ad-Hoc meetings.

- Scientific Research Committee 1 meets on the first Tuesday of every month.
- Scientific Research Committee 2 meets on the second Wednesday of every month.
- Scientific Research Committee 3 meets on the third Tuesday of every month.
- Scientific Research Committee 4 meets on the fourth Wednesday of every month.

VI. NEW PROTOCOLS

Submissions:
Protocols that are submitted to the SRC for review will require documentation of internal departmental protocol review and protocol prioritization by the department prior to SRC submission. Internal review/prioritization must be documented in the Department Chair’s Protocol Review and Prioritization Memo prepared and signed by the relevant Department Chair (or Division Head, if the Department Chair is the protocol’s Principal Investigator). The memo should address specific required elements, including the date the protocol was reviewed by the department, potential impact of the medical/scientific question; strength of preclinical data underlying the clinical hypothesis, contribution of the investigators at MD Anderson, data from the department to demonstrate accrual feasibility (e.g., past history of similar trial accrual), data and/or evidence to justify economic feasibility, placement in the Department/Center/CCSG Program priority list, and inclusion of competing protocols with their expected closure dates. The Protocol Review and Prioritization Memo template and access to the related protocol document will be sent automatically to the Department Chair through the online protocol submission system.

The memo and other related documentation and correspondence must be submitted at the time the protocol is submitted through the on-line system. This information will be reviewed initially by the Vice President, Clinical Research Administration or a designee, to ascertain that the required elements have been completed. Principal Investigators will receive timely feedback if specific memo elements require additional detail, which must be submitted and deemed acceptable before the protocol can proceed through the review process.

New protocols must be submitted through the on-line system by the designated submission deadlines, as stated on the Office of Protocol Review and Reporting intranet site at MD Anderson. The Office of Protocol Review and Reporting will not accept any new protocols until the Principal Investigator has submitted all required items with the original protocol for review.

Required items include:
- Department Chair Protocol Review and Prioritization Memo signed by the Department Chair/Division Head (if the submitting PI is the Department Chair)
- Signature of Principal Investigator (PI)
- Collaborator’s Signature - Listed protocol collaborators should be limited to only those investigators who are key participants in the design, conduct and/or analysis of the trial. Investigators whose roles will be limited to accruing patients to the study should not be listed as collaborators, allowing them to remain in the pool of nominated medical reviewers or the designated Content Expert Reviewer. These investigators may be listed as sub-investigators on the Statement of Investigator, Form FDA 1572, when appropriate for the study.
- Names of two nominated medical reviewers OR a designated Content Expert Reviewer listed on the Department Chair Memo.
- Protocol
- Abstract
- Required MDACC Appendices:
• Protocol Checklist
• Departmental Prioritization List with submitted protocol listed
• Investigator Brochure (IB) – only required for IND protocols

• Relevant Appendices, if available (i.e.: Performance Scales, Study Questionnaires, Pharmacy Manual, etc.)
• Informed Consent

**Approved MDACC Biostatistical Collaborator:** Only needed for MDACC investigator-initiated studies. The MDACC Biostatistical collaborator must sign the collaborator page in PDOL before the Office of Protocol Review and Reporting (OPR&R) will accept the protocol. The biostatistical collaborator’s signature indicates that the biostatistician acknowledges actual collaboration on the study and that the protocol’s statistical design is complete and ready for review.

**Clinical Content Template (CCT):** All protocols that are using an ordering tool will need to submit a completed CCT in the Cherwell system prior to the study being submitted to the SRC for review. If the CCT is not there at the time of submission, the protocol will be rejected back and not be allowed to proceed forward until the CCT has been submitted.

**MDACC IND:** If MDACC will be holding the Investigational New Drug (IND) application for the newly submitted protocol, the PI / regulatory staff must contact the MDACC IND Review office prior to SRC submission. The protocol will go through an abbreviated review process. Once sign off has been obtained, then the protocol can be submitted to the SRC for review. If the protocol is submitted and has not been through the abbreviated review process, the protocol will be removed from the SRC submission cycle until further notice.

**Department Review Option / Content Expert Reviewer:**
Clinical departments have the option to replace the two existing nominated medical reviewers now with one disease-specific departmental reviewer (Content Expert Reviewer (CER)). In order to participate in the Department Review Option / Content Expert Review process, clinical departments must have a structured internal review process for all new concepts and/or protocols that includes a faculty meeting presentation and an evaluation of the following review criteria: study design and rationale, feasibility and accrual, and priority and impact. Clinical departments approved to utilize this new option will receive an institutional approval memorandum verifying their qualifying status, which must be included along with their request. All request must be submitted via the Department Chair Protocol Review and Prioritization Memo at the time of submission.

The department review must be submitted by a non-collaborating faculty member who has participated in the departmental review process and has agreed to submit a summary of the departmental level critiques and approval decisions regarding the new concept and/or protocol. The non-collaborating faculty member should be a faculty member that is not currently listed as a Co-Investigator or Collaborator on the newly submitted protocol. The department must also ensure that this reviewer does not have a financial conflict of interest with the sponsor and supporter of the study. Departments that utilize this option will not be required to appoint additional faculty reviewers for the protocol submission and, in some instance the Principal Investigator may also be exempt from the review of another protocol during this submission cycle.

**Scientific Review Process:**
New clinical protocols will be reviewed for scientific merit, biostatistical approach, pharmaceutical quality, and for any other characteristics deemed appropriate by the SRC Co-Chairperson. This review will be performed by either two Medical Reviewers or a Content Expert Reviewer as well as other multidisciplinary reviewers such as Diagnostic Imaging, Interventional Radiology, Pharmacy, Nursing, and the Quantitative Sciences Division. Additionally, other administrative reviews of the study will be conducted to ensure that institutional requirements are met, including parallel reviews by the IND Office, CLIA, Office of Human Subjects Protections Consent Editors, the Office of Protocol Support and Management for multi-center issues, the Office of Protocol Review and Reporting for an OPR&R Admin Review, Environmental Health and Safety (E.H. &S.) as well as Clinical Research Finance. The SRC Chairperson of the specific SRC meeting...
will assign the nominated medical reviewers / content expert reviewer. If a clinical protocol has
been received for review and has quality of life questionnaires attached, the Chairs of the
Psychosocial, Behavioral, and Health Services Research Committee (PBHSRC) will assign a
Medical 3 reviewer who will focus on a questionnaire review.

A protocol cannot be discussed at the SRC meeting unless there has been a written response
from the Principal Investigator to the reviewers’ comments, all agreed-upon changes have been
documented in the protocol documents, and the protocol has been resubmitted through the on-
line system back to the SRC committee. If the reviewer and the PI are at an impasse on an
issue, the reviewer can allow the protocol to move forward to the SRC meeting for discussion.
All collaborators’ signatures must be obtained before the protocol can be placed on the SRC
meeting agenda.

If the PI is responding to a SRC disapproval and the protocol is a first-time resubmission (i.e.,
after having been disapproved in a previous SRC review, see “Protocol Dispositions” below), the
cover memo must list all previous critiques and details and how the previous concerns have been
addressed, in addition to addressing the required elements of the Department Chair’s Protocol
Review and Prioritization Memo. The SRC Co-Chairperson may table a discussion or postpone
presentation to the committee if, in his/her opinion, the reviewers’ comments have not been
sufficiently addressed by the Principal Investigator.

When the protocol is ready to be presented at the SRC meeting, the SRC the Co-Chairpersons
will assign a primary discussant to summarize the reviews and present a suggested impact score
for each protocol that will be presented at the upcoming SRC meeting unless it is a PI initiated
protocol. If it is a PI initiated protocol, then primary and secondary discussants will be selected
for review.

**Meeting Process:**
The SRC meetings will consist of open and closed sessions. During the open session, the
Principal Investigator, will give a brief summary of his/her protocol and respond to specific
questions from the SRC members. If the PI is unable to present due to another conflict, a Co-
Principal Investigator, Collaborator, or Department Chair can present on his/her behalf. Following
the discussion, the Principal Investigator or Presenter as well as any collaborators/research staff
and non-SRC-member reviewers will be asked by the Co-Chairperson to leave the room while
the committee discusses the protocol.

During the closed session, the primary and / or secondary discussants will summarize and score
the protocol’s scientific merit and feasibility using the Clinical Trial Assessment and Prioritization
Worksheet (Discussant Memo). The Worksheet provides the committee members with specific
elements to evaluate and score for each protocol; all scores will be averaged to derive an overall
impact score to be recorded for each protocol. The overall impact scores can be rounded up or
down, depending on the number behind the decimal (i.e.: .5 or higher will be rounded up to the
next whole number). Each committee member will be allowed one score per protocol. All
electronic scoring is done anonymously.

**Scoring for New Protocols:**
Instructions to the SRC members will be provided by the SRC Co-Chairperson regarding overall
impact scores that will allow the protocol to be Approved, Approved with Minor Concerns,
Approved with Major Concerns, Disapproved, or Rejected. The discussants will review and score
the protocols on a scale of 1-5, with 1 having the highest merit and 5 having the lowest merit.
Discussants’ comments will be a part of the SRC closed session. Only voting members of the
SRC will be allowed to score each protocol that is being presented at the SRC meeting. All
scores will be kept confidential within the SRC and IRB members only.

**Protocol Dispositions:**
The PI of the study will be notified of the SRC outcome through the on-line system within 2 days
following the meeting. The previous (if a protocol resubmission) and final SRC recommendations
for each approved protocol will be forwarded to the IRB. There are five different dispositions that will result from the committee's discussions and protocol scoring (note the previous categories of potential SRC review outcomes are in parentheses for reference).

Overall Impact Score of 1: (Revised from “Approved”): The protocol is approved without modification and will proceed to an upcoming IRB meeting.

Overall Impact Score of 2: (Revised from “Approved with Minor Concerns”): The protocol will not proceed to an upcoming IRB meeting; PI responses to minor concerns may be addressed with an administrative review by SRC Co-Chair(s).

Overall Impact Score of 3 (Revised from “Approved with Major Concerns”): The protocol will not proceed to an upcoming IRB meeting, and will require substantive revisions by the PI. Once the protocol has been resubmitted, the SRC Chair will do an administrative review and let the SRC meeting coordinator know if the protocol is ready for SRC presentation. If so, then the protocol will be placed on the next available meeting agenda.

Overall Impact Score of 4 (Revised from “Disapproved”): The PI is allowed one resubmission of the protocol if desired. A new Department Chair’s Review and Prioritization Memo and a full SRC review of the resubmission resulting in a score of 1 or 2 will be required to allow the protocol to move forward to the IRB. Efforts will be made to assign resubmitted protocols to the same SRC that initially disapproved the protocol, as well as to the same primary and/or secondary discussants.

Overall Impact Score of 5 (Revised from “Rejected”): No resubmissions of the protocol will be allowed. (See Appeals process)

Rejected Study Appeals:
A PI may initiate an appeal of a SRC impact score of 5 (i.e., “rejection”) for a reviewed protocol. Appeals must be submitted through the online protocol document system as a memo from the respective Department Chair, and include: 1) date of SRC review; 2) justification for one resubmission of the referenced protocol, addressing specific SRC review critiques as relevant (1-page limit); and 3) electronic signature of the Department Chair. Appeals will be reviewed by an Appeals Committee comprised of the Vice President and Deputy Chief Academic Officer, Clinical and Interdisciplinary; Vice President, Clinical Research Administration; and the SRC Co-Chair(s) of the respective SRC. A successful appeal would convert the SRC outcome to an Impact Score of 4 (i.e., “disapproved”), allowing one resubmission, with no further appeals allowed.

VII. CONFLICT OF INTEREST:
SRC members are expected to follow the SRC Member Conflict of Interest Policy. The SRC agenda will include the name of the Sponsor for each protocol discussed. It is expected that members of the SRC who may have a conflict with the Sponsor of a specific protocol will recuse themselves from the deliberations surrounding that protocol. A conflict includes a financial interest in the performance or outcome of a specific clinical trial. The SRC Specialist will record the recusal in the official SRC minutes. The SRC Specialist will verify in the institutional COI database that a financial conflict does not exist for primary and secondary reviewers (See Appendix A).

VIII. IPCT PROTOCOLS:
All protocols that have a PI or co-PI who is from the Institute for Personalized Cancer Therapy (IPCT) (whether they are clinical or lab-based protocols), or protocols that are funded by the IPCT must be sent to the SRC for review. The review will follow the specified scientific review process course as described above.
IX. **CLINICAL PROTOCOLS THAT CAN BYPASS OF SRC:**

Protocols that contain one of the following elements may be eligible to bypass the SRC review process and meeting. The PI will be able to select the most appropriate category for the protocol when it is originally created in the online system. The protocol will be electronically submitted directly to the IRB for review. If the IRB chair or designee determines that the protocol requires scientific review, then the protocol will proceed through the SRC process. Protocols included are:

- Phase II Expansion Study (Phase 1 and II components were approved by the MD Anderson SRC and IRB)
- No patients will be enrolled at MDACC – Data Analysis Only
- Expanded Access Study
- Humanitarian Use Device (HUD)
- Utilization of radiation therapy services that are being provided as part of the agreement with the Texas Children’s Hospital (TCH) and Baylor
- Patients will receive standard of care procedure(s) or radiation therapy at MD Anderson as part of their enrollment on a non-MD Anderson study
- Protocols that are using a Central IRB.

PI’s that can provide written documentation that the newly submitted protocol has already been through a Scientific Review Process at another NCI Cancer Institute can request to bypass the SRC process at MD Anderson. The Vice President, Clinical Research Administration will review the documentation and make the final determination. When approved, the protocol will be handed over to the IRB for review.

X. **COOPERATIVE GROUP PROTOCOLS:**

Protocols that are Cooperative Group based but are funded by a foundation or a pharmaceutical protocol will need to go through a full scientific review process at MD Anderson before proceeding forward to the IRB for review.
Appendix A

Standard Operating Procedure
Scientific Research Committee (SRC) Member Conflict of Interest Recusal from Committee Deliberations

The purpose of this procedure is to provide guidance for the management of Scientific Research Committee (SRC) members' conflicts of interest (COIs) while ensuring that the most experienced members' knowledge informs decisions on the scientific value of research protocols.

1. The SRC agenda and/or protocol lists will include the names of for-profit entities involved in each protocol being reviewed. The SRC Co-Chairperson will poll the SRC members about potential conflicts of interest prior to the start of discussion of each protocol and members' responses will be documented in the meeting minutes.

2. For the following situations of COI, SRC members are required to recuse themselves from participating in discussions and from voting. In these situations, the SRC member must leave the room prior to discussion and voting, and their departure will be documented in the minutes. SRC members with a COI will be invited to return to the room when voting is concluded. These situations include:

   a. Protocols for which the SRC member is the principal investigator or co-principal investigator

   b. Protocols involving any product from a for-profit entity in which the SRC member, or any member of that member's immediate family, has any equity interest or serves as a member of the involved Board of Directors. (Mutual funds, blind trusts, and family members' equity interests not known to the SRC member are excluded.)

   c. Protocols involving any product from a for-profit entity from which the SRC member has received cash payments or other remuneration exceeding $10,000 in the previous 12 months.

3. For the following situations of conflict of interest, SRC members may participate in discussions after declaring their potential conflicts of interest to the committee members who are present. In these situations, the SRC members may remain in the room during voting, but must abstain from voting. These situations include:

   a. Protocols for which the SRC member is a co-investigator or collaborator.

   b. Protocols for which the principal investigator is a member of the SRC member's department(s).