Scientific Review Committee (SRC) Procedures

Submission and Pre-Review

1. Principal Investigator (PI) and study staff submit protocol via electronic protocol system, Protocol Document On-Line (PDOL).
2. SRC Coordinator will do a quick administrative review to make sure all required information has been submitted and determines which committee should review the protocol.
3. Vice President Clinical Research Administration (VPCRA) will review the Department Chair Protocol Review and Prioritization Memo and make a determination if the protocol can proceed forward through the SRC review process.
   a. If approved, then the protocol can proceed.
   b. If not approved, the protocol is then rejected back to the PI and study staff for additional corrections.
      i. PI and study staff will need to make the corrections and resubmit the protocol back to the SRC.
         1. VPCRA is then notified that the protocol is ready to proceed forward.

Review and Approval Process:

4. SRC Coordinator inputs pertinent data into the electronic database, Clinical Oncology Research system (CORe).
5. Protocol is accepted and Status is changed in the electronic protocol system (PDOL) to CRC Sent to Reviewers.
6. SRC Coordinator will send out VPCRA determination memo with pertinent deadline dates for the submission cycle to the PI and study staff.
7. New Protocol List is sent out to the Ancillary Reviewer contact group and access is granted in the electronic protocol system (PDOL).
8. SRC Chair assigns either Medical Reviewers or Content Expert Reviewer and access is granted in the electronic protocol system (PDOL).
9. PI and study staff will start receiving critiques on their newly submitted protocol.
   a. If no issues noted, then the PI and study staff do not need to respond back to the reviewers.
   b. If issues or questions are noted, then the PI and study staff will need to respond.
      i. Reviewer(s) will review the PI’s response and either give their approval to proceed forward or bring up additional concerns.
10. PI and study staff will need to make any agreed upon changes to the protocol documents before proceeding forward to the SRC Meeting.
a. If this is a sponsored protocol, the change can be implemented in the next protocol amendment.

11. PI and study staff resubmits protocol back to the SRC.

12. SRC Coordinator will review the revised protocol documents to make sure all agreed upon changes have been made.
   a. If ready to proceed forward, the protocol is then accepted and the status is then changed to Pending CRC / PBHSRC Review.

**Meeting Process**

13. The SRC Chair sets the upcoming meeting agenda and selects Discussant reviewer(s). Discussant reviews are blinded to the PI and study staff and are only available to SRC and IRB members in their review packets.

14. The PI and study staff are then notified of the protocol presentation time for the upcoming SRC meeting.

15. During the open session of the SRC meeting, the PI will give a brief synopsis of the protocol and reviews received, and answer any questions that the Committee might have regarding the protocol.
   a. If the PI is unable to present, the Department Chair, Co-Principal Investigator, or Collaborator can present on behalf of the PI.

16. During the closed session, the Committee will hear from the Discussant(s) and vote on the protocol.

17. The PI and study staff will be notified of the Committee’s decision with 48 hours of the SRC meeting.
   a. If the protocol receives an overall Impact Score of a 1 (Approved), it will proceed to the Institutional Review Board (IRB).
   b. If the protocol receives an overall Impact Score of a 2 (Approved with Minor Concerns) –
      i. The PI and study staff must create a generic memo responding to the meeting contingencies via the electronic protocol system, PDOL.
      ii. Protocol documents will need to be revised before resubmitting back to the SRC.
      iii. The SRC meeting coordinator will review the revised documents and send to the SRC Chair for an administrative review.
      iv. SRC Chair must give their final approval, prior to the protocol being forwarded to the IRB.
   c. If the protocol receives an overall Impact Score of a 3 (Approved with Major Concerns)-
      i. The PI and study staff must create a generic memo responding to the meeting contingencies via the electronic protocol system, PDOL.
      ii. The PI and study staff will need to revise the protocol documents and resubmit back to the SRC.
iii. The SRC meeting coordinator will review the revised documents and send to the SRC Chair for review.

iv. SRC Chair will review and provide an administrative sign off before the protocol can be placed on a SRC meeting agenda.

v. The PI will be notified of their presentation date and time.

d. If the protocol receives an overall Impact Score of a 4 (Disapproved)-
   i. The PI and study staff must create a generic memo responding to the meeting contingencies via the electronic protocol system, PDOL.
   ii. The PI and study staff will need to revise the protocol documents and submit a new Department Chair Protocol Review and Prioritization memo before resubmitting back to the SRC.
   iii. The SRC meeting coordinator will review the revised documents and send to the SRC Chair for review.
   iv. SRC Chair will review and provide an administrative sign off.
   v. The VPCRA will also review the newly submitted Department Chair Protocol Review and Prioritization memo.
   vi. Once sign off has been obtained by the VPCRA and the SRC Chair, the protocol will be sent back out for a re-review. The protocol will undergo another SRC review process (including review and approval, and meeting).

e. If the protocol receives an overall Impact Score of a 5 (Rejected), the protocol cannot proceed forward at MD Anderson. (See Appeals Process)
   i. Appeals Process:
      1. A PI may initiate an appeal of a SRC impact score of 5 (i.e., “Rejected”) for a reviewed protocol. Appeals must be submitted through the electronic protocol system (PDOL). A generic memo from the respective Department Chair should 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 Research; Vice President Clinical Research Administration; and the SRC Co-Chair(s) of the respective SRC.
         a. 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.
         b. If not successful, then the protocol stops.
Contact Information:

Jenny L. Gay, BS, CCRP
Manager, Human Research Regulations
Office of Protocol Review and Reporting (OPR&R)

jlgay@mdanderson.org
T: 713-563-5438
SRC Helpdesk: crcpbhscr@mdanderson.org
OPR&R Mainline: 832-750-6777