

# Protocol Review & Monitoring System

## Standard Operating Procedures

Title: **SRC Coordination and Meeting Conduct**

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**PURPOSE:** The purpose of this procedure is to describe the standard steps and timelines for scheduling SRC meetings, documenting attendance and assigning reviews.

**SCOPE:** This SOP applies to the Protocol Review and Monitoring System (PRMS) staff, responsible for administrative conduct of the Scientific Review Committee (SRC).

**PERSONNEL RESPONSIBLE:** Principal Investigators (PIs) and/or applicable study staff responsible for submitting SRC review applications through ePRMS in OnCore as required per SRC policy. The Manager of PRMS and OnCore Oncology is responsible for conducting ePRMS training for anyone who requires access to ePRMS prior to access being granted. The SRC Coordinator will review and process submissions for review as defined in SRC policy. The Scientific Review Committee (SRC) will perform scientific reviews of ePRMS submissions as applicable per SRC policy. The SRC will provide updates to the Director and Associate Director of Clinical Research, Fred & Pamela Buffett Cancer Center.

**REFERENCES:** SRC Policies and Procedures, V12 dated 12/22/2020

### **PROCEDURES:**

#### Meeting Invitations:

- Each monthly full board meeting must be sent via calendar invite, directly from the PRMS Office email, immediately following the most recent full board meeting. It is up to the discretion of the SRC Coordinator who has responsibility for creating the Zoom meeting and sending the calendar invitation
  - Each calendar invite must include the Zoom meeting information, and instructions to RSVP by specific deadline
  - Calendar invites should be set to request responses
  - A **second reminder** should be sent in one week to those who have not RSVP'd, and should include a second deadline for response
  - If SRC members still have not responded by the monthly Thursday submission deadline, a **final reminder** should be sent to the remaining members with a 24-hour deadline for response. Copy the Chair and Vice-Chair on the final reminder. Those that do not respond should be noted as not attending with a comment that no response was received
- As members RSVP, update the attendance spreadsheet immediately with their attendance status, as well as any applicable information regarding their attendance (i.e. able to attend but not able to review)
  - If reviewers attendance status changes, update the attendance spreadsheet with the updated status immediately and note the changes in the comment field

## Reviewer Assignments:

- The SRC Coordinator must complete tentative reviewer assignments by the Wednesday immediately following the submission deadline, at the latest, for approval by the Chair and Vice-Chair
  - The assignments may be sent via email for approval, or reviewed at the Wednesday Administrative meeting, at the request of the Chair and/or Vice-Chair
- The SRC Coordinator must complete any corrections to the reviewer assignments by the Thursday immediately following the submission deadline
- Upon completion of final reviewer assignments, the SRC Coordinator must notify the Regulatory Data Associate (RDA) to update applicable documents
- The RDA will update reviewer worksheets and the agenda with the reviewer assignments, and must be completed by noon on the Friday of the week following the submission deadline. Upon completion, the RDA will notify the SRC Coordinator
- The SRC Coordinator will verify accuracy of the reviewer assignments on the worksheets and agenda. Any corrections should be sent to the RDA for immediate resolution
- After the reviewer sheets and agenda have been updated successfully, the SRC coordinator will load applicable documents into ePRMS, assign reviewers in ePRMS as defined in the ePRMS Coordinator Quick Guide, and send reviewer assignment email to SRC Committee Members
  - This should be completed by the end of business day on the Friday of the week following the submission deadline, but **no later than the Monday, one week prior to the next scheduled full board meeting, at noon.**

## Meeting Conduct:

- The SRC Coordinator and RDA should be co-hosts for meetings conducted in Zoom
- The SRC Coordinator must have video capability for full board meetings conducted in Zoom
- Either the RDA or the SRC Coordinator will share their screen during full board meetings, with the following documents and applications ready for review:
  - Agenda
  - ePRMS Console
  - New Protocols:
    - ePRMS Console information
    - Protocol
    - Reviewer sheet (only if requested by the reviewer)
    - Additional documents on request of the SRC
  - Continuing Review:
    - SRC Submission form (accrual table)
    - ePRMS Console information
    - Reviewer sheet (only if requested by the reviewer)
    - Additional documents on request of the SRC
  - Request for Change:
    - Summary of Changes
    - SRC Submission form (if the change includes changes to the information built in the CTMS)
    - Reviewer sheet (only if requested by the reviewer)
    - Additional documents on request of the SRC
- The SRC Coordinator must be ready to address questions from the committee during the meeting and direct the RDA to navigate to appropriate documents or sections, as applicable

## Full Board Meetings: Attendance, Minutes and Review Letters

- Upon conclusion of a full board meeting, the SRC Coordinator or RDA should forward review letters for all submissions receiving full board approval to the Chair/Vice-Chair for signature
- The RDA will create a letter template for all other reviews not receiving full approval and notify the SRC Coordinator when it is complete.
- The SRC Coordinator will review the completed reviewer sheets and comments from the full board meeting, and draft the non-approval letter with conditions for approval.
  - These letters should be ready for review at the Wednesday Administrative Meeting immediately following the full board meeting

- For more complicated reviews, the SRC Coordinator may request the SRC Chair and/or Vice-Chair assist in writing the conditions in a non-approval letter
    - Once complete, send the non-full approval letters to the Chair/Vice-Chair for signature.
    - Notify the RDA when the final letters are complete
- The RDA will create the draft of the SRC minutes, including review decisions and vote counts. Upon notification of final letters for studies that did not receive full approval from the SRC Coordinator, the conditions defined in each letter are to be added to the minutes
- The review results and letters to be documented in ePRMS as follows:
  - The “action date” in ePRMS should be the date the review occurred (date the Chair or Vice-Chair reviewed an expedited review, or the date of the full board meeting). Note: the action **should not be** the date of the letter. There may be a delay from when the review occurred to when the letter was drafted and sent
  - The “renewal date” should be entered as 1 year from the date of the “action date” for all continuing reviews
  - The vote counts should be entered to match the minutes
  - Enter any applicable review notes in the comments field
  - Upload the review letter as a document
- The SRC Coordinator or RDA must document SRC Member attendance in ePRMS
  - Navigate to ePRMS Coordinator Console>Agenda>search for full board meeting date>select display>select attendance
  - Select the box for each member who attended the full board meeting, hit submit

#### Ongoing

- The SRC Coordinator will process submissions within 1-2 business days of submission for the following:
  - Ensure minimum submission requirements have been met as defined in SRC policy, query the submission for missing requirements or outstanding questions, ensure the protocol was built via the study intake process and not created separately through ePRMS
  - Assign appropriate level of review for the submission (i.e. full board vs expedited)
  - Notify the RDA once administrative review is complete, and again when reviewer assignments are complete/approved as noted above
  - Perform QA of SRC review letters, review sheets, agenda and minutes
- Regulatory Data Associate
  - Prepare the appropriate review sheet, based on submission and review type
  - Add submission to the appropriate section of the agenda
  - Prepare an approval letter
  - Add full board reviewer assignments to the agenda and review sheets once upon notification from the SRC Coordinator as noted above

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