

The Fred Hutch and University of Washington Cancer Consortium relies on its Protocol Review and Monitoring System (PRMS) two-stage review mechanism to review cancer-related interventional trials. The first stage is the [Research Group Review](#), and second stage is the [Scientific Review Committee](#) (SRC). The two stages work together to provide a complementary review, but each has a distinct role in the review process and a clearly defined scope.

The Research Groups complete the required first-stage review of concepts and protocols, prioritizing trials for their patient population to reduce the number of studies that are low-accruing due to competing trials.

Research Group Structure

The Cancer Consortium established Disease and Modality Research Groups, along with each appointed Director, Co-Directors, and Admin contacts, can be found on the [Cancer Consortium website](#).

Important: Changes in Research Group Directorship and/or Admin support contacts must be communicated to Clinical Research Support via PRMS@fredhutch.org as soon as possible.

Designees may lead reviews if the Director has a conflict of interest or is unavailable. Conflict of interest details can be found in the [Data and Safety Monitoring Plan](#). Research Groups build their own rosters and review processes, and multidisciplinary attendance of each review is strongly recommended.

Research Group Review Documentation

The Research Group Review is documented in the Research Group Information Summary for SRC Form (RGR Form) available at: <https://redcap.link/rgr>.

Only one completed RGR Form can be provided for SRC submission regardless of the number of Research Groups involved in the protocol. The primary Research Group must be identified in the form and all other collaborating groups and attendees can be noted as collaborating Research Groups and/or participating disciplines.

Important: Ensure all potential collaborating Research Groups are included in the RGR Form based on the protocol's eligibility and inclusion criteria. This includes, but is not limited to:

- *If the primary Research Group is a Modality Group, at least one collaborating Disease Group must be included.*
- *Protocols eligible to participants under the age of 18 must include Pediatric Oncology as a collaborating Research Group if Pediatric Oncology is not already the primary Research Group.*

Once the RGR Form is complete, REDCap will generate an email notification with a PDF attachment. This PDF must be included in the submission for SRC review. Recipients of the REDCap notifications are the primary and collaborating Research Group Directors and Admin contacts, Principal Investigator, Director or Designee responsible for the protocol's review, and the submitter and other contacts added in the REDCap RGR Form.

Important: Old versions of the RGR Form and forms with incomplete fields or a REDCap time completion stamp of greater than three months before SRC submission will not be accepted. RGR Forms that are not accepted must be redone and will therefore delay the protocol's SRC review timeline.

Returning to a Saved RGR Form

The “Save & Return Later” button in REDCap allows for preparation of the RGR Form before review or saving a partially completed form if multiple team members or reviewers need to collaborate on its completion. A Return Code and Survey Link will be generated, and you can send the survey link to others during the review and RGR Form completion process. Ensure the Return Code is noted as it’s required to access and edit the form.

Your survey responses were saved!

You have chosen to stop the survey for now and return at a later time to complete it. To return to this survey, you will need both the *survey link* and your *return code*. See the instructions below.

1.) Return Code
A return code is ***required*** in order to continue the survey where you left off. Please write down the value listed below.

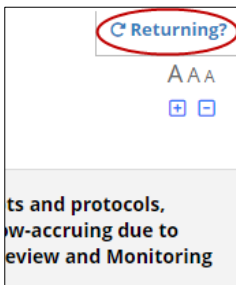
Return Code

* The return code will NOT be included in the email below.

2.) Survey link for returning
You may bookmark this page to return to the survey, OR you can have the survey link emailed to you by providing your email address below. For security purposes, **the return code will NOT be included in the email**. If you do not receive the email soon afterward, please check your Junk Email folder.

* Your email address will not be associated with or stored with your survey responses.

To return to a saved form, use the Survey Link provided when you or a team member last saved the form, or you may go to <https://redcap.link/rgr> and click the Returning? link in the upper right corner. Then, enter the Return Code to reopen the form to continue. If you lose the Return Code, contact PRMS@fredhutch.org for assistance.



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CANCER CONSORTIUM

Research Group Review Summary for SRC Form

To continue the survey, please enter the RETURN CODE that was auto-generated for you when you left the survey. Please note that the return code is ***not*** case sensitive.

If returning to update an already completed form, you may use the same process above. An updated form after the initial completion will *not* resend the automatic notifications. Ensure you’ve sent a copy to yourself and all others who need one using the Send Confirmation Email option. If the updates were requested by the SRC, the new PDF will need to be provided in OnCore.

Enter your email to receive confirmation message?
A confirmation email is supposed to be sent to all respondents that have completed the survey, but because your email address is not on file, the confirmation email cannot be sent automatically. If you wish to receive it, enter your email address below.

* Your email address will not be associated with or stored with your survey responses.

Rejected Protocols

It is critical for Research Groups to report rejected protocols to demonstrate the rigor of our two-stage PRMS. All rejected protocols should be reported regardless of funding source or reason for rejection.

Rejections can be reported at <https://redcap.link/rgr> using the "Research Group rejected this protocol with no further consideration" option.

Rejections can also be reported by emailing RejectedProtocols@fredhutch.org with the following information:

- Research Group rejecting the trial (*Must be one of the established [Research Groups](#)*)
- Protocol title
- Reason for rejection
- Date rejected (*If exact date is unknown, please provide the month and year*)
- Sponsor

Reminders and rejected protocol summaries will be sent out on an ongoing basis. If there are additional Research Group members or administrative staff to include on the distribution list, notify RejectedProtocols@fredhutch.org.

References

1. NCI/NIH: PAR-21-321 – Cancer Center Support Grants (CCSGs) for NCI-designated Cancer Centers
2. CC Plan: [Data and Safety Monitoring Plan of the Fred Hutch/UW/Seattle Children's Cancer Consortium](#)
3. [Research Group Review Information Summary for SRC Form](#)
4. CRS Definitions Dictionary

Version Number	Current Effective Date	Original Effective Date
02	06/18/2024	06/26/2023

Appendix 1: Workflow to complete the [Research Group Review Information Summary for SRC form](#)

