

PROTECT Tip Sheet for Research Teams: “Preparing Scientific Review Submissions”

Scientific Review at NIH IRP

Scientific Review at NIH IRP includes the initial concept and full protocol review, annual and quadrennial review of the ongoing protocol, and review of substantive amendments to the protocol that pose new scientific questions. These reviews become a part of the protocol record and are made available to the IRB and NIH leadership.

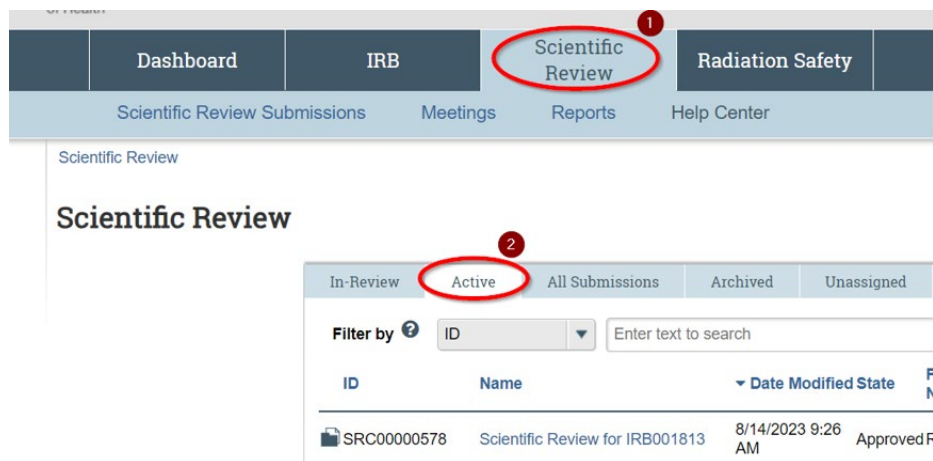
[Scientific Review Policy](#): This policy describes when Scientific Review is required.

[Scientific Review SOP](#): This SOP describes what is required of each Scientific Review type. This SOP was approved by the NIH IRP Chief Scientific Officer.

Questions regarding Policy and Procedures: If you have questions about whether scientific review is required or what additional documents are required for scientific review, contact the Scientific Review Coordinator in your IC.

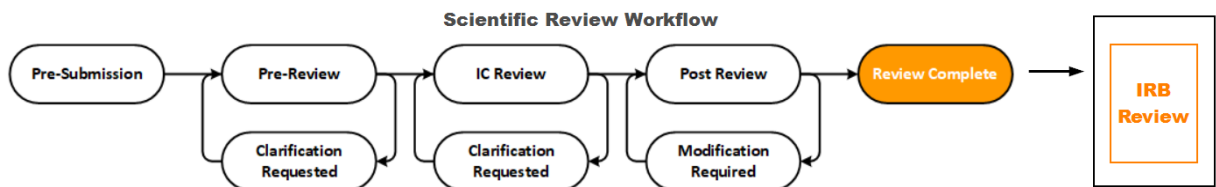
Scientific Review in PROTECT

Scientific Review has its own full project in PROTECT, much like the IRB project. This means that it has its own workflow, states, email notifications, roles, SR committees, minutes, letters, SR specialists, SR reviewers, SR “offices” (or ICs), etc. Currently approved (or “active”) Scientific Review submissions can be located under the *Scientific Review* tab > *Active* tab.



When Scientific Review occurs

Initial Submissions or Modifications, when they require Scientific Review, are completed prior to submitting the submission to the IRB. The system will “block” the IRB submission from being submitted to the IRB until the scientific review is completed. These reviews are part of the IRB workflow.



Annual or Quadrennial Reviews take place when required by your IC and are not tied in PROTECT to IRB submission of continuing reviews at all. These are not part of the IRB workflow in any way.

Ancillary reviews that are done on Scientific Review

Scientific Review Submissions	
Lab Chief/ Branch Chief/ Accountable Investigator	Not Blocking Should be managed by study team prior to IRB submission, if required by IC.
Clinical Director/ (Or IC Director/ Scientific Director - if CD has conflict)	Not Blocking Should be managed by the SRC Coordinator after SRC approval, but before the final SR approval letter is sent.
Chief Scientific Officer	Not Blocking Should be managed by SRC Coordinator after SRC approval, but before final SR approval letter is sent.

User Guides

The PROTECT system contains user guides for each Scientific Review user type (or 'role'): Researchers, Reviewers, Committee Staff, and Chief Scientific Officer. These guides contain detailed click-for-click steps and can be found in PROTECT as shown below using the numbered steps. In addition, a summary of 'Quick Steps' that go into completing scientific review by each role are on the next page.

Name	Description
SRC Approved Scientific Review Process in Protect	Standard Operating Procedure for the conduct of IRP Scientific Review
SRC CSO Guide	A step-by-step guide for the tasks performed by the Chief Scientific Officer.
SRC Meeting Management Guide	A step-by-step guide for SRC staff and committee participants that includes well as recording decisions.
SRC NIH Reports Guide	A step-by-step guide on generating standard and advanced reports, applyi
SRC Researcher's Guide	A step-by-step guide for the study staff that includes creating and submittin responding to clarification requests.
SRC Reviewer's Guide	A step-by-step guide for SRC reviewers that includes finding and reviewing accessing the meeting agendas, and submitting the review.
SRC Staff Guide	A step-by-step guide for the tasks performed by the SRC Staff.
SRC Submissions for Migrated Studies	A step-by-step guide for how to initiate scientific review in PROTECT for st

Scientific Review 'Quick Steps':

NOTE: See relevant user guides above for specific instructions. In addition, 'Quick Steps' are below.

Scientific Review 'Quick Steps'	
PI/PI proxy	<p>Drafts IRB application and answers YES to 'SR Required'</p> <p>Creates SR application from IRB workspace</p> <p>Uploads any IC-specific forms</p> <p>Uses <i>Manage Ancillary Review</i> on SR workspace to assign: Lab Chief/Branch Chief/Accountable Investigator</p> <p>Informs PI to review submission and submit</p>
PI	<p>Reviews for completeness and Submits to Scientific Review <i>(NOTE: <u>Only PI can Submit SR submissions</u>)</i></p>
SRC Specialist	<p>Conducts their pre-review of form and documents</p> <p>Requests any clarifications</p> <p>Assigns full or expedited review per SR policy</p> <p>Assigns reviewers per review type</p> <p>Documents SR outcome and drafts minutes and letter</p> <p>Using <i>Manage Ancillary Review</i>, obtains Clinical Director sign off (or IC Director, if CD has a conflict)</p> <p>Using <i>Manage Ancillary Review</i>, notifies Chief Scientific Officer that SR is ready for their review and acceptance</p>
Chief Scientific Officer	<p>Conducts their review</p> <p>Submits their acceptance via <i>Submit Ancillary Review</i></p>
SRC Specialist	<p>Sends final SR outcome letter to Study Team</p>

Completing a MOD, ANNUAL, or QUAD SR for the first time in [Migrated](#) iRIS Studies (Where initial SR review was done in iRIS)

When we migrated iRIS studies over to PROTECT, we did not migrate over their initial scientific reviews. Because there is not already an initial SR in the PROTECT system for migrated iRIS studies, we have modified the SR forms in PROTECT for those studies so you can upload your initial SR approval that was completed in iRIS.

We created a tip sheet when we went live for [how to complete your first scientific review for a migrated protocol](#).

IMPORTANT: Always consult this tip sheet when doing your first scientific review in PROTECT for a migrated iRIS study. It tells you WHERE to initiate the SR depending on which type of SR required at this time (MOD/QUAD/ANNUAL), and HOW to answer the questions on the SR form.

HOW TO INITIATE SCIENTIFIC REVIEW IN PROTECT FOR MIGRATED STUDIES THAT DO NOT HAVE AN INITIAL SCIENTIFIC REVIEW IN THE SYSTEM

Scenario 1: IRB MOD or MOD/CR for IRB study does not have an SRC requirement flag set, but the parent IRB study does not have an associated SRC Initial Review.

SAMPLE

Migrated IRB studies will have the "is Scientific Review Required" flag populated to either TRUE or FALSE.

This scenario applies to the following conditions:

- 1) Migrated IRB study (parent IRB study has an SRC requirement flag set upon migration and the flag is set to TRUE, and there is no SRC Initial Review submission tied to the parent IRB study), or
- 2) Natively created IRB study (parent IRB study has the SRC requirement flag set to NO, and there is no SRC Initial Review submission tied to the parent IRB study)

Flow:

1. An IRB MOD/CR is created from an active IRB study workspace. On the IRB MOD/CR SmartForm, it is indicated that a Scientific Review is required.



2. On the IRB MOD/CR workspace, a project creator button for "Initiate SRC Modification" appears.



3. Because there is no SRC Initial Review submission in the system that is tied to this IRB study, on the first page of the SRC Modification SmartForm, the following questions are asked:
 - Select the scientific review committee
 - Attach a copy of the approved SRC initial review form
 - Select the study type



This tip sheet covers two scenarios:

Scenario 1: IRB MOD or MOD/CR requires SRC review, but the parent IRB study does not have an associated SRC Initial Review in PROTECT yet.

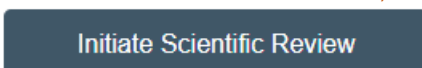
FROM IRB MOD/CR WORKSPACE, use this button:



Scenario 2: SRC Annual or Quadrennial Review needs to be created, but the parent IRB study does not have an associated SRC Initial Review in PROTECT yet.

NOTE: You will have to keep track of when SR annual/quad is due as PROTECT will not send out reminder notifications for your first one. Once you get your first annual/quad approved, you will however receive reminders moving forward.

FROM IRB PARENT STUDY WORKSPACE, use this button:



Completing SR submissions for New PROTECT Studies

(Or migrated studies that had their first SR in the system using the scenarios above)

Scenario 3: Initial Scientific Review of a new study

FROM IRB PARENT STUDY WORKSPACE, use this button:

Initiate Scientific Review

Scenario 4: IRB MOD or MOD/CR requires SRC review

FROM IRB MOD/CR WORKSPACE, use this button:

Initiate SRC Modification

Scenario 5: SRC Annual or Quadrennial Review is required

FROM YOUR ACTIVE SR WORKSPACE, use these buttons:

Create Annual Review

Create Quadrennial Review

Support

For additional questions or help using the PROTECT system, please [submit a PROTECT Help Desk ticket](#) and our IT staff will assist you.