

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/CR for an IRB Study requires an SRC review, but the parent IRB study does not have an associated SRC Initial Review

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)

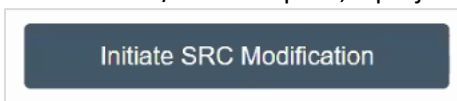
Flow:

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.



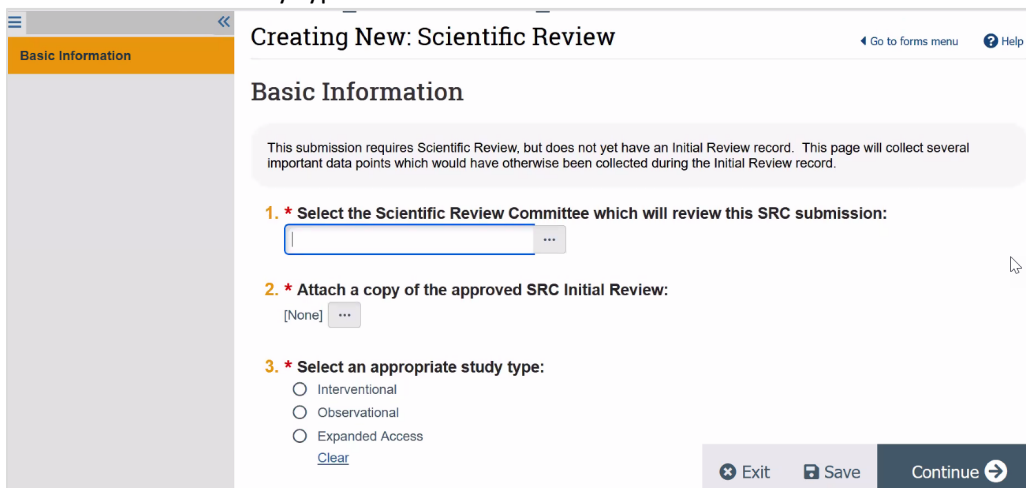
* Is Scientific Review required for this modification or continuing review?
 Yes No [Clear](#)

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



Creating New: Scientific Review

Basic Information

This submission requires Scientific Review, but does not yet have an Initial Review record. This page will collect several important data points which would have otherwise been collected during the Initial Review record.

1. * Select the Scientific Review Committee which will review this SRC submission:
[Dropdown menu]
2. * Attach a copy of the approved SRC Initial Review:
[None] [Dropdown menu]
3. * Select an appropriate study type:
 Interventional
 Observational
 Expanded Access
[Clear](#)

Exit Save Continue

4. Clicking “Continue” will branch the user to the remaining SRC Modification SmartForm.

Validate Compare << **Modification Information** Go to forms menu Print Help

Basic Information

Modification Information

Submission Documents

The following fields are displayed from IRB. Any changes to these fields should be performed in IRB.

Study Number:
IRB000326

Follow-On Submission Number:
MOD000160

Modification Summary:

Currently Approved Total Accrual Ceiling (at all NIH sites):
100

Requested Accrual Ceiling (at all NIH sites):
100

1. * Did the Milestone Plan change?
 Yes No [Clear](#)

2. * Did the Common Data Elements (CDE) Applicability change?
 Yes No [Clear](#)

3. * Did the Disease Community Partnership and Study De:
 Yes No [Clear](#)

Exit Save Continue

5. Note that the submission type of this SRC submission is “Initial Review” because this is the first SRC submission that is tied to this IRB study. After this SRC submission is approved, Annual Review or Quadrennial Review can be created from the workspace of this SRC submission.



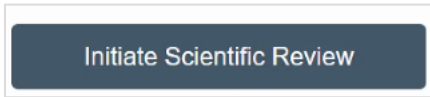
Scenario 2: SRC Annual or Quadrennial Review needs to be created, but the parent IRB study does not have an associated SRC Initial Review

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

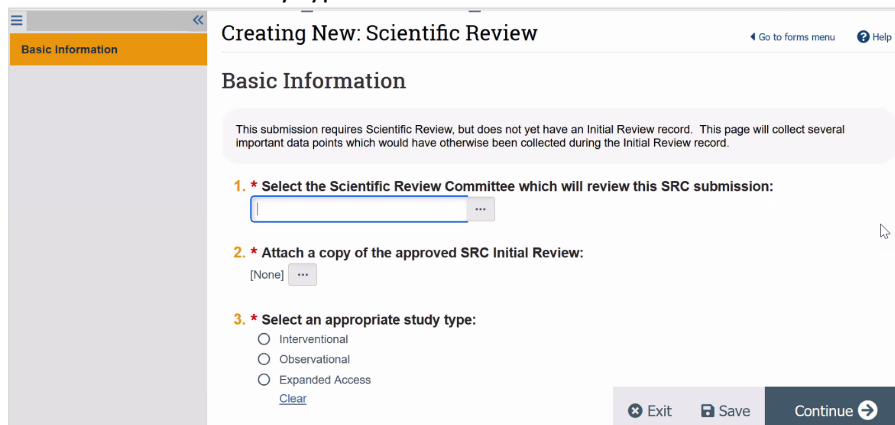
This scenario only applies to the migrated IRB study condition where the parent IRB study has an SRC requirement flag set upon migration and the flag is set to TRUE, and there is no SRC Initial Review submission tied to the parent IRB study.

Flow:

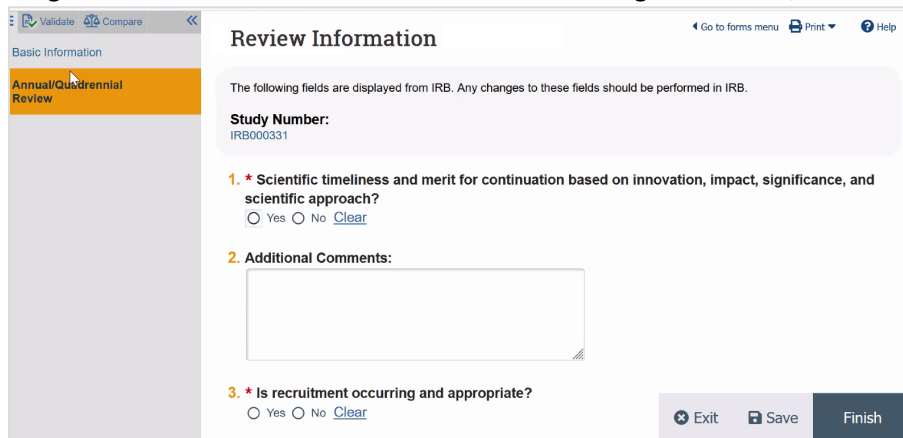
1. On a workspace of a migrated IRB Study, a project creator button for “Initiate Scientific Review” appears.



2. 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 SmartForm, the user will be asked the following questions:
 - Select the scientific review committee
 - Attach a copy of the approved SRC initial review form
 - Select the study type



3. Clicking “Continue” will branch the user to the remaining SRC Annual/Quadrennial Review SmartForm.



4. Note that the submission type of this SRC submission is “Initial Review” because this is the first SRC submission that is tied to this IRB study.

Edit Scientific Review

Printer Version

Manage Ancillary Reviews

Assign Office

Submit

Add Comment

Principal Investigator: Mark Roschewski

SRC Submission Type: Initial Review

IRB Parent Study:

SRC Office: CENTER FOR CANCER RESEARCH

SRC Committee: Scientific Review Board - NCI-CCR

SRC Specialist: Natalie Washington

Letter:

Letter:

