

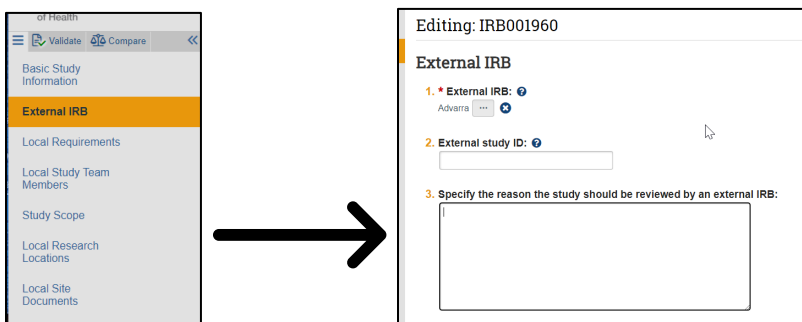
PROTECT Tip Sheet for NIH Research Teams:

Tips & Tricks: Relying on an External IRB (NCI CIRB specific)

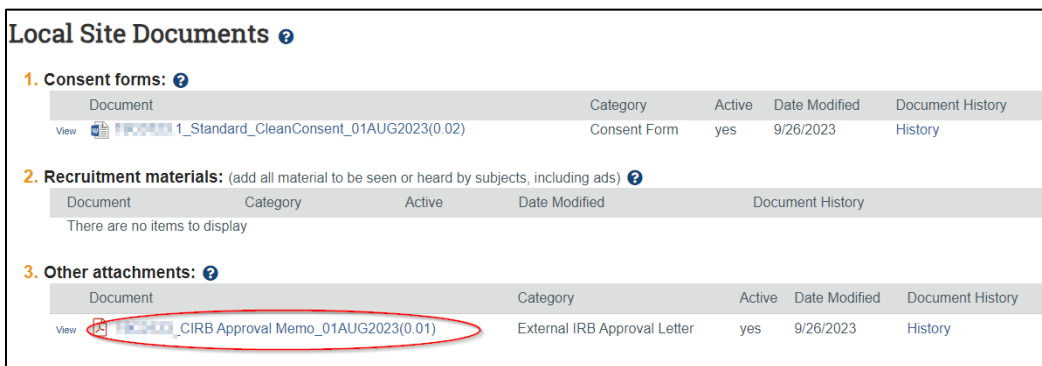
Creating a New Study:

NCI-CIRB-reviewed Single-Site Study (NIH is the only site)

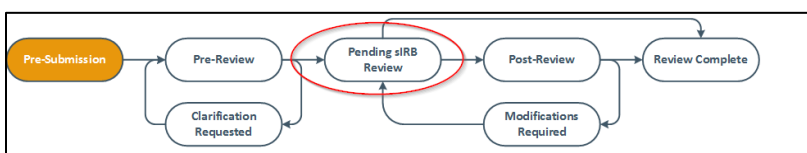
- The study form for external IRB studies is almost identical to an NIH IRB study form with just a few differences. For the NCI CIRB only, this is created in PROTECT **after** the NCI CIRB has already reviewed and approved the protocol at the NIH site.
- There is an external IRB section of the form to list information about the external IRB:



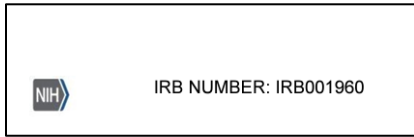
- The external IRB approval letter(s) confirming that NIH has been approved as a Participating Site in the study should be attached in the **“Other attachments”** section of the **Local Site Documents** in the study form and categorized as an **“External IRB Approval Letter”**.



- Instead of having an IRB Review area of the workflow, **“Pending sIRB review”** takes its place after the external IRB has provided approval (happens in pre-review state):



- The approved NIH site consent(s) will be stamped with the NIH IRB number.



- After IRB coordinator records the sIRB decision, an acknowledgement letter is sent to the study team. The study state will transition to “External IRB”.

ACKNOWLEDGEMENT OF AN EXTERNAL IRB UPDATE

DATE: September 28, 2023

TO: Alic [REDACTED]

RE: IRB001 [REDACTED]

Dear Alic [REDACTED]

The IRB Office reviewed the following updated information for “Row [REDACTED]”
 Co [REDACTED] is relying
 on an external IRB:

Site Information	
Type of Review:	NIH Institutional Review (post-review)
Reviewing IRB:	NCI Central IRB
Submission ID:	IRB001 [REDACTED]
Site	Alic [REDACTED]
Investigator:	Alic [REDACTED]



External IRB

Entered IRB: 12/29/2022 9:24 AM
 Initial approval: 4/22/2019
 Initial effective: 4/22/2019
 Effective: 9/26/2023
 Approval end: 12/19/2023
 Last updated: 11/22/2023 4:41 PM

NCI-CIRB-reviewed Multi-Site study (NIH is a participating site)

- The process of creating a new study is the same for multi-site external IRB studies, but once the new study is acknowledged, the study state will transition to “Active.”

Active

Entered IRB: 11/2/2021 11:20 AM
 Initial effective: 3/22/2021
 Effective: 7/25/2023
 Approval end: 12/19/2023
 Last updated: 11/30/2023 4:36 PM