End User Guide: SIFTER

Study Intake Form To Expedite Research

Overview

SIFTER, which resides within eIRB, serves as a centralized repository for study start-up information required to support various processes associated with the initiation of a new study in OnCore Clinical Trial Management System. The study start-up information collected within SIFTER is intended to supplement new study information already being collected within eIRB. Unlike other eResearch modules, SIFTER was designed to provide the ability to submit any sub- project independently, rather than needing to satisfy all the requirements on each smart form and submit as a whole.

Each area below represents a SIFTER sub-project:

Sub-Project	Description	Process Owner(s)
1.01 OnCore	Supports data collection needed to build an OnCore protocol and calendar.	OnCore Support Team
1.02 Budget	Supports data collection needed to develop a budget in OnCore.	CTFM Budget Analysts
1.03 Contracts	Supports data collection needed for the development of a clinical trial agreement.	Clinical Research Contracts Administration (CRCA)
1.04 Drug Information	Supports data collection needed for studies which involve drugs / biologics or placebos.	Investigational Drug Service
1.05 Payments	Supports data collection needed if study participants or parents will receive any type of reimbursement / compensation for study participation.	CTFM Registration and Charge Review Analysts
1.06 Epic Study Build	Supports data collection needed to complete the build of study records, manage study team access to study records and develop order sets and / or operational tools in Epic.	PARC Support and Epic Care Core Clinical
1.07 Laboratory	Supports data collection needed for studies that require laboratory testing and / or sample processing.	Pathology and Laboratory Medicine

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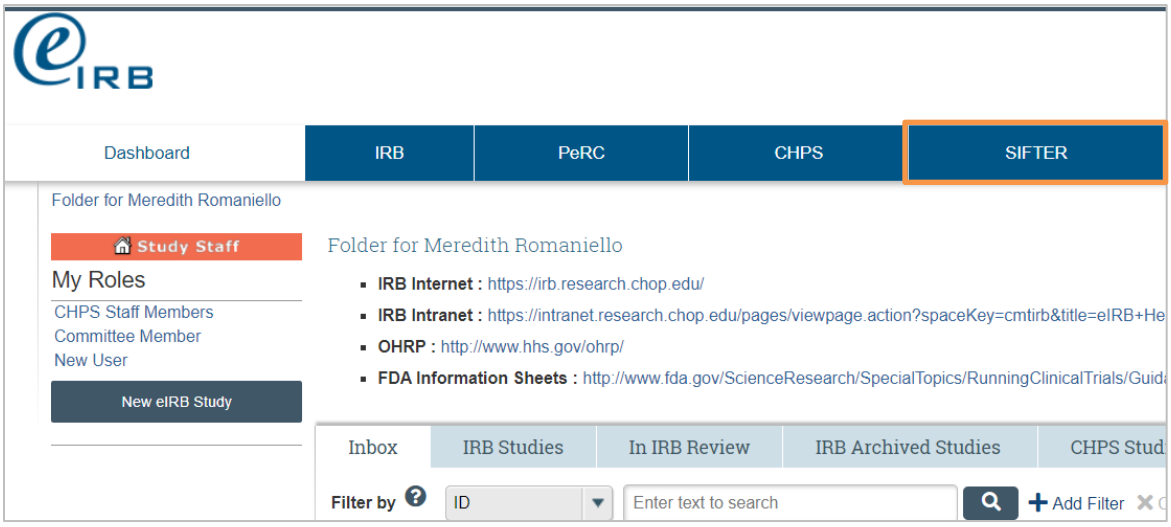
In addition, SIFTER is also used to support information gathering related to amendments which may involve changes to the OnCore protocol calendar and / or budget, changes to the contract, changes that would impact Epic Research and changes that would impact the Investigational Drug Service or Laboratory Services. The information collected within a SIFTER amendment is intended to supplement amendment information already being collecting within eIRB.

Accessing SIFTER

Please Note: SIFTER is not part of the IRB. Please direct all questions / concerns related to SIFTER to oncore@chop.edu.

To access SIFTER, login to eIRB: https://eirb.research.chop.edu/eIRB and then select the SIFTER tab.



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Creating a New SIFTER for Study Start-Up

To create a new SIFTER record for the purpose of providing study start-up information, there are 3 possible options:

- ***New eSIFTER & eIRB Study***: Use this option to create both a SIFTER record **AND** IRB study record for brand new studies that currently do not exist within SIFTER, eIRB or OnCore.

- ***New eSIFTER From Existing eIRB Study***: Use this option to create a new SIFTER record that is linked to an existing study in eIRB.

- ***New eSIFTER From Your Existing eIRB Study***: If you are listed as the CHOP Study Coordinator or Principal Investigator for an existing study in eIRB, use this option to create a new SIFTER record that is linked with one of these studies.

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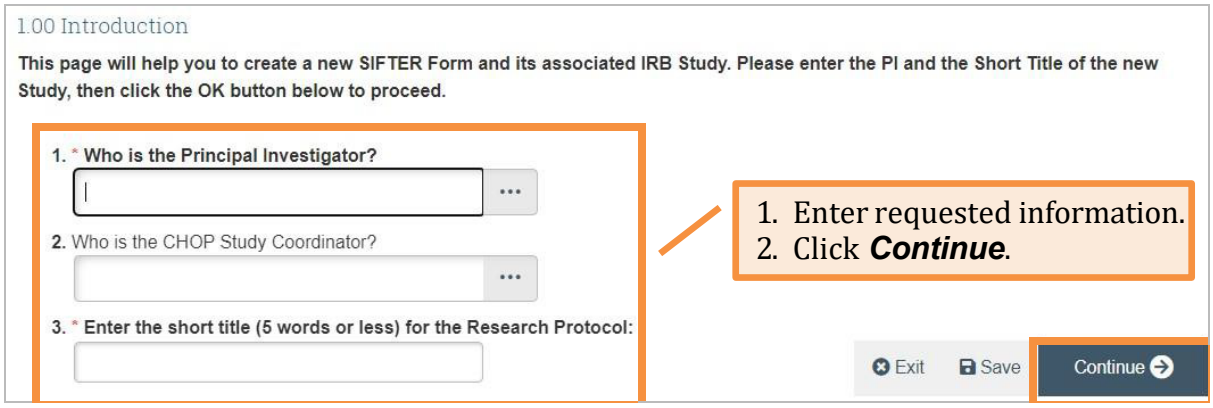
New eSIFTER & eIRB Study

Upon selecting ***New eSIFTER & eIRB Study:***

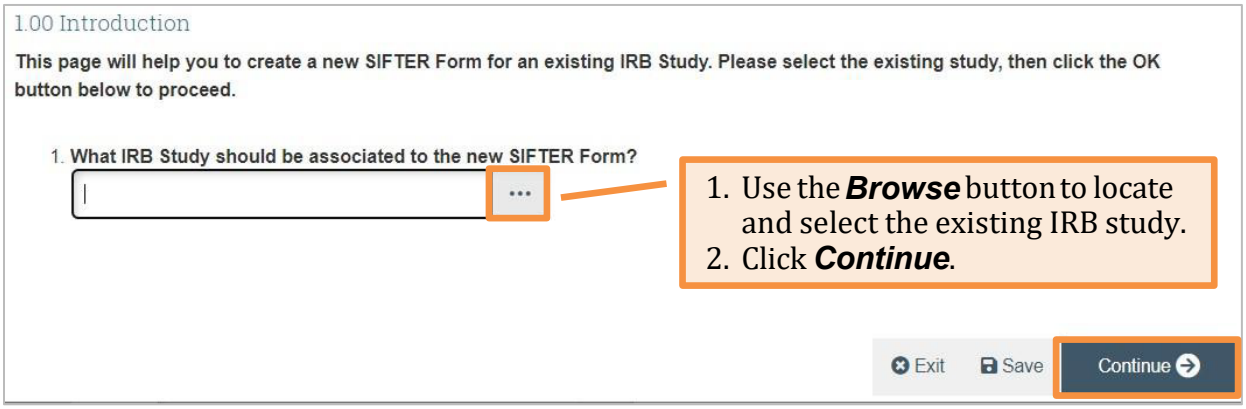


You have just created a new SIFTER record **AND** its associated eIRB study. By default, you will advance to the smart form for the first SIFTER sub-project – 1.01 OnCore, where you can begin completing the necessary data entry. All smart forms are editable and will reflect a status of *Pre-Submission*.

- Click ***Save*** to retain existing data entry without submitting.
- Click ***Continue*** (or use the smart form navigation pane on the left side of the page) to move to the next / desired smart form to begin data entry.
- Click ***Exit*** to return to the study's SIFTER workspace.

New eSIFTER From Existing eIRB Study

Upon selecting ***New eSIFTER From Existing IRB Study:***



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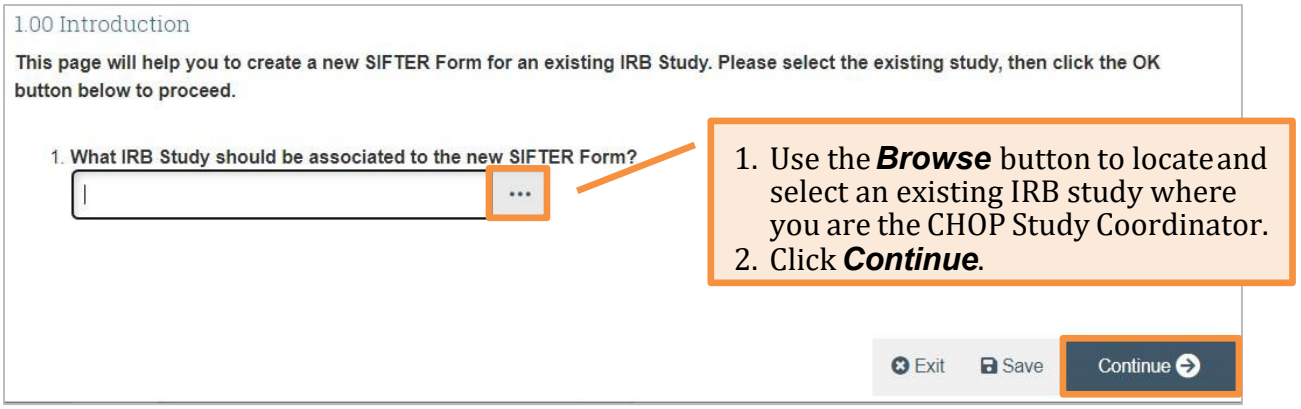
You have just created a new SIFTER record from an existing eIRB study. By default, you will advance to the smart form for the first SIFTER sub-project – 1.01 OnCore. All smart forms are editable and will reflect a status of *Pre-Submission*.

- Click ***Save*** to retain existing data entry without submitting.
- Click ***Continue*** (or use the smart form navigation pane on the left side of the page) to move to the next / desired smart form to begin data entry.
- Click ***Exit*** to return to the study's SIFTER workspace.

New eSIFTER From Your Existing eIRB Study

Upon selecting ***New eSIFTER From Your Existing IRB Study:***



You have just created a new SIFTER record from one of your existing eIRB studies. By default, you will advance to the smart form for the first SIFTER sub-project – 1.01 OnCore. All smart forms are editable and will reflect a status of *Pre-Submission*.

- Click ***Save*** to retain existing data entry without submitting.
- Click ***Continue*** (or use the smart form navigation pane on the left side of the page) to move to the next / desired smart form to begin data entry.
- Click ***Exit*** to return to the study's SIFTER workspace.

Please Note: If the existing IRB study has already been built in OnCore and you are creating this new SIFTER record to request a change, it is not necessary to complete data entry within the main SIFTER sub-projects (1.01 – 1.07). Email oncore@chop.edu and let us know that you need to submit a SIFTER Amendment. We'll administratively submit the main SIFTER sub-projects (1.01 – 1.07), so that you can access the SIFTER Amendment smart form.

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Please Note: There are many shared questions between SIFTER and eIRB. When a new SIFTER record is created from an existing IRB study, shared questions will be automatically populated within SIFTER. While the IRB study remains in a pre-submission state, shared questions may be answered / edited in either SIFTER or eIRB. Once the IRB study has been submitted, SIFTER will evaluate the current smart form path of the IRB study and editing will need to occur as follows:

- Shared questions which are included in the current IRB smart form path will become non-editable in SIFTER and any necessary edits must be made in eIRB.
- Shared questions which are not included in the current IRB smart form path will remain editable in SIFTER.

Shared questions can be easily identified in SIFTER by looking for the icon. By clicking on the icon, SIFTER will display a message which indicates the status (editable vs non-editable) of a shared question.

This question is linked to your IRB study.
If you need to edit this answer, please do so on your IRB study.
This question is shared with eIRB; however, it remains editable in SIFTER as it is not included on a page that is displayed in the current smart form path of the main eIRB study.

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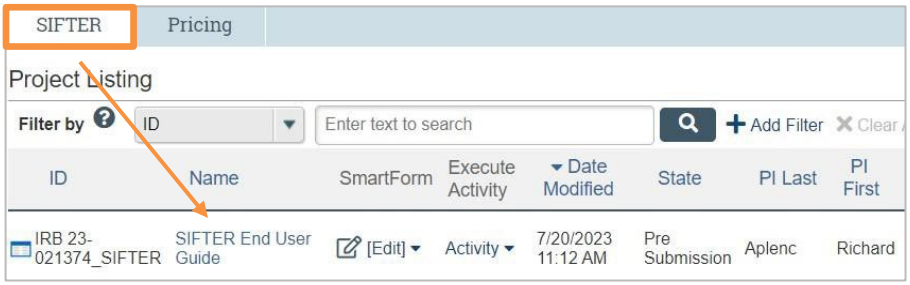
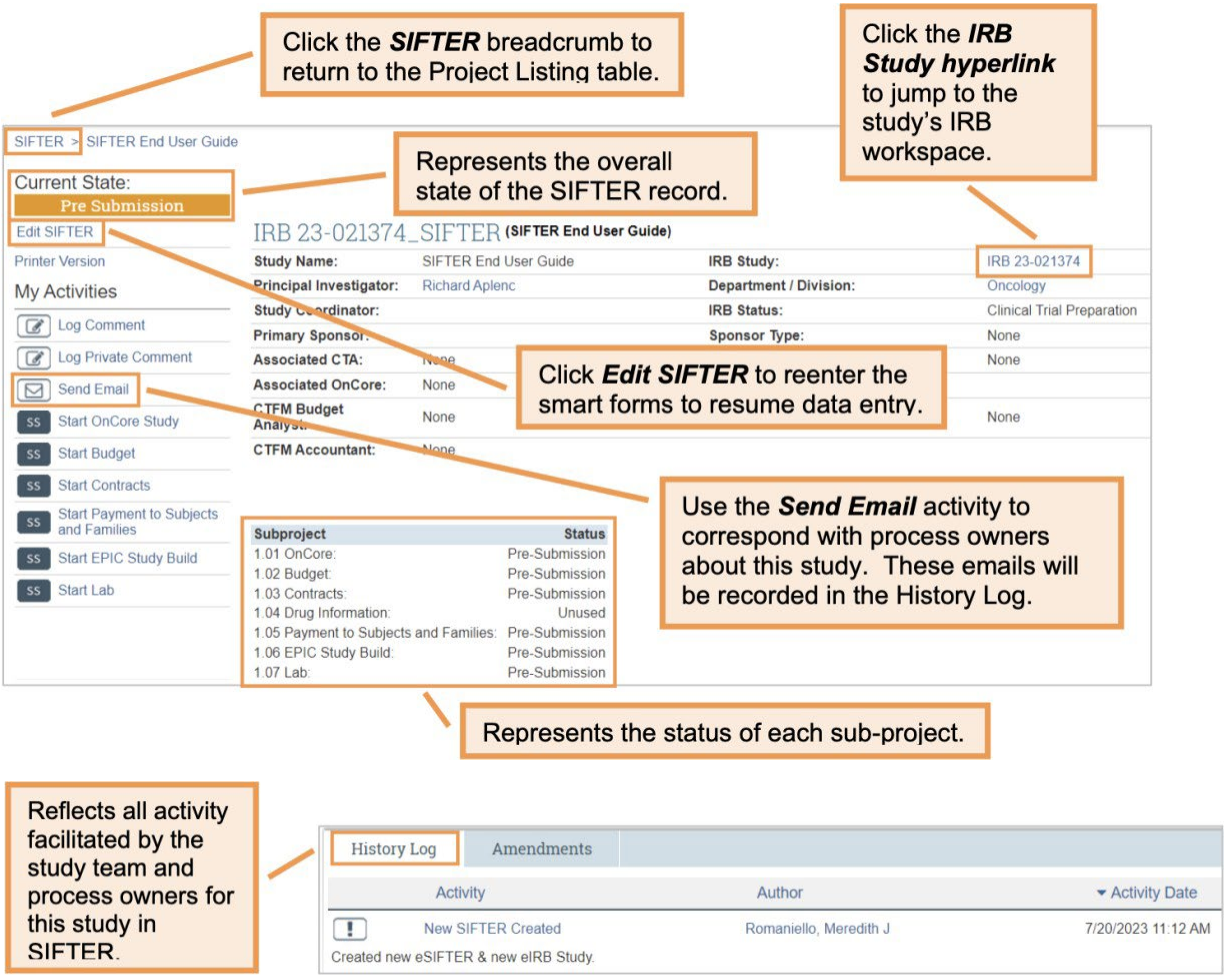
SIFTER Workspace

Once you have created a new SIFTER record, it can be easily accessed by selecting it from the ***SIFTER*** tab > Project Listing table > Name column hyperlink. **Note**: The ID assigned to a SIFTER record will always be the IRB No_SIFTER.



Upon clicking the desired Name hyperlink, you'll enter the selected study's SIFTER Workspace.



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Tips for Completing Data Entry within SIFTER Sub-Projects

SIFTER has been designed using a feature called ***Hide & Show***. This feature allows us to only "show" questions which would be required under certain circumstances, thus eliminating the need for a user to answer unnecessary / inapplicable questions. Therefore, it may be necessary to provide answers to certain questions first, so that SIFTER will display the other required questions, which may exist within another sub-project.

The ***Hide & Show*** relationships / prerequisites are described for each SIFTER sub-project below, if applicable.

1.01 OnCore: There are no hide & show relationships / prerequisites.

1.02 Budget: The questions required for industry funders versus non-industry funders are slightly different. Therefore, prior to beginning data entry within 1.02 Budget, you must:

1. Provide an answer to 1.01 OnCore, Q6 - Who is the primary funder? and click Continue.
    a. The 1.02 Budget smart form has now been customized to reflect either the industry or non-industry budget-related questions as applicable.

1.03 Contracts: The questions required for industry funders versus non-industry funders are slightly different. Therefore, prior to beginning data entry within 1.03 Contracts, you must:

1. Provide an answer to 1.01 OnCore, Q6 - Who is the primary funder? and click Continue.
    a. The 1.03 Contracts smart form has now been customized to reflect either the industry or non-industry contracts-related questions as applicable.

1.04 Drug Information: This smart form is only required for studies that involve drug, biologic and / or placebo. Therefore, if this is applicable, prior to beginning data entry within 1.04 Drug Information, you must:

1. Select Drug / Biologic or Placebo as an answer for 1.02 Budget Non-Industry, Q26 or 1.02 Budget Industry, Q22 - Does the study involve any of the following for research purposes only (not clinical care)? and click Continue.
    a. The 1.04 Drug Information smart form is now available for data entry.

1.05 Payment to Subjects & Families: There are no hide & show relationships / prerequisites.

1.06 Epic Study Build: There are no hide & show relationships / prerequisites.

1.07 Laboratory: There are no hide & show relationships / prerequisites.

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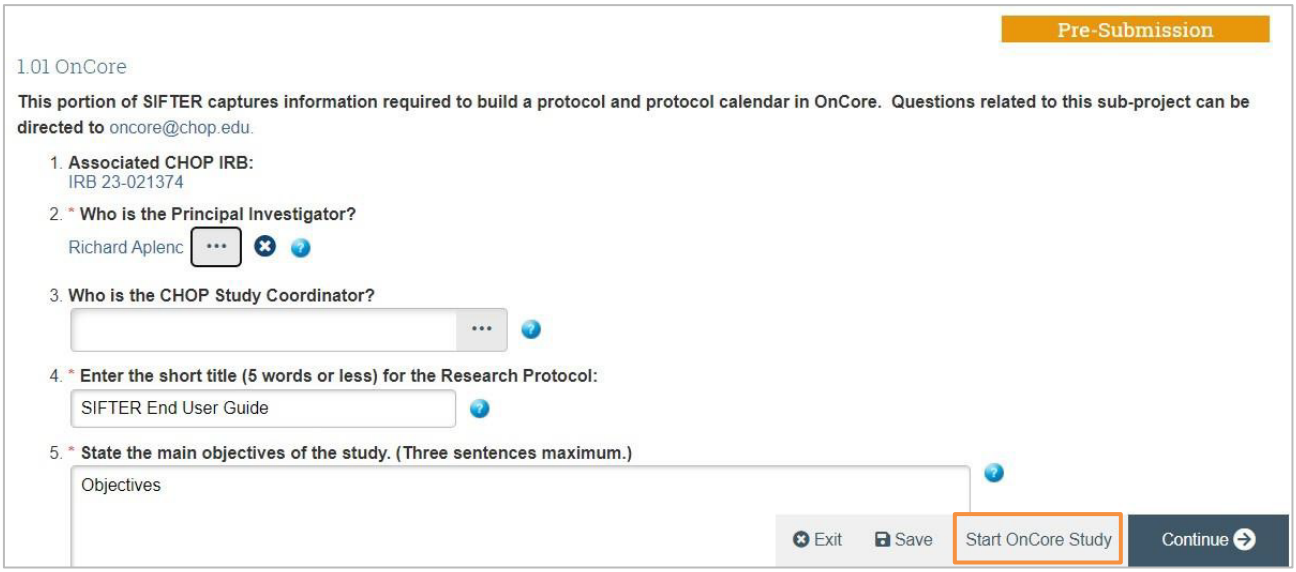
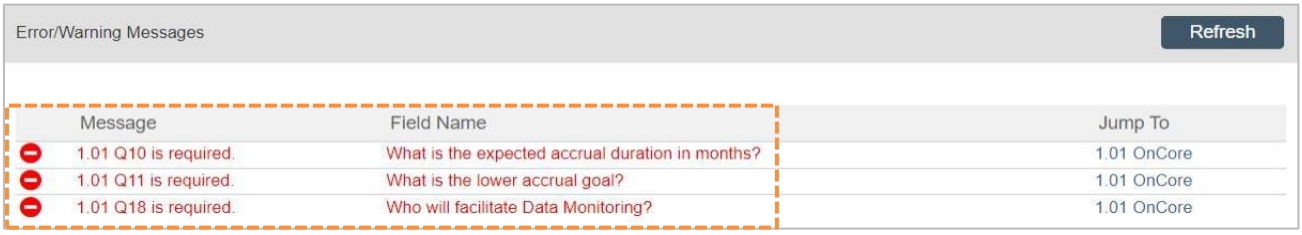
Submitting SIFTER Sub-Projects

Each sub-project in SIFTER will be submitted individually. When data entry is complete within a smart form, select the ***Start XXXXX*** button in the lower right of the page to submit.



Upon clicking the Start XXXXX button, SIFTER will perform data validation on the smart form being submitted. If applicable, an Error / Warning Messages pop-up window, like the one below, will display required fields, which will need to be addressed prior to submission. Once all Errors / Warnings have been addressed, click the Start XXXXX button again.



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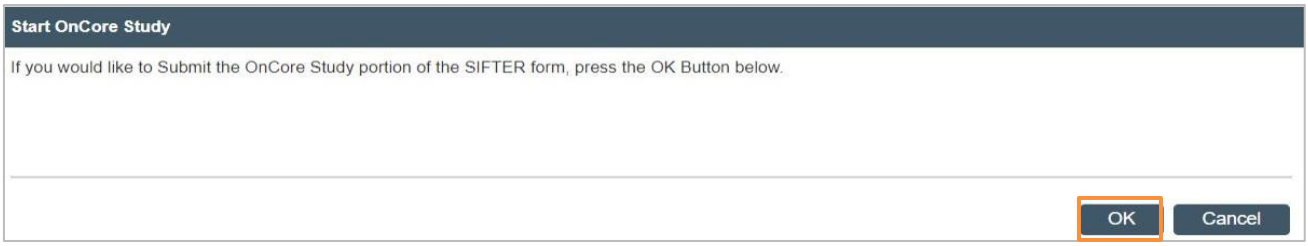
When data validation is successful and there are no errors / warnings, the pop-up window below will display. Click ***OK*** to confirm submission of this smart form.



The smart form status has been updated to ***Submitted*** and it is no longer editable.

Note: The process owner(s) for the submitted SIFTER sub-project will receive an ACTION REQUIRED autogenerated email notification alerting them that new information is now available for this study in SIFTER.

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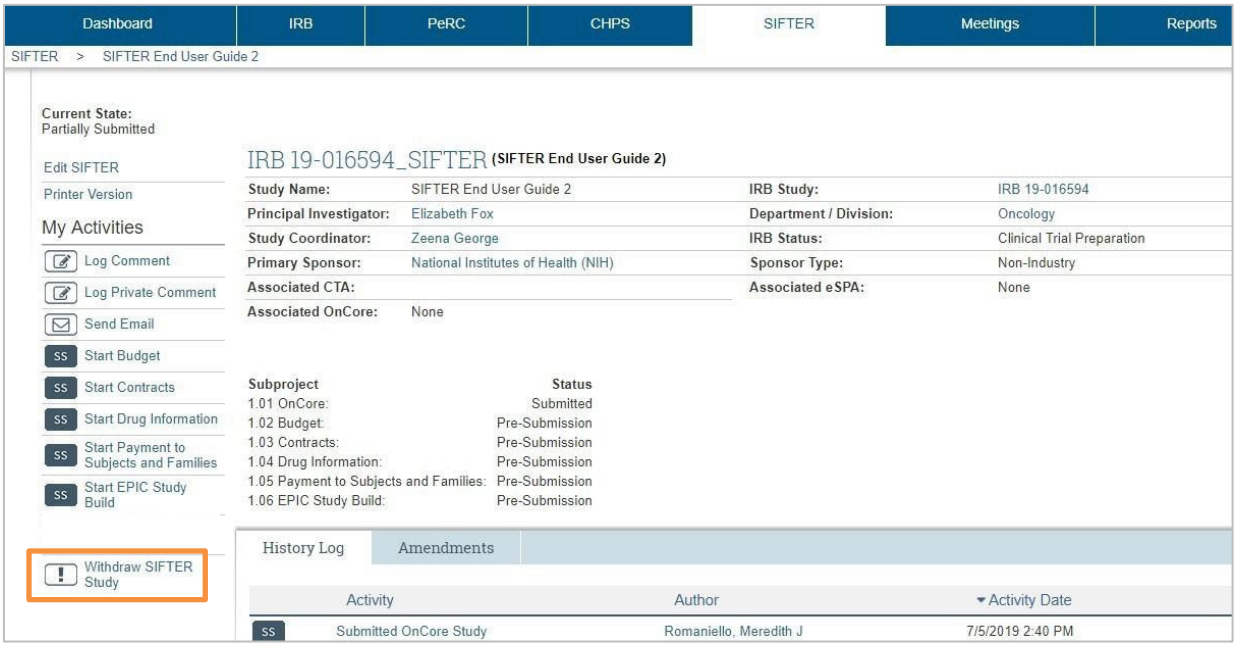
Withdrawing a SIFTER Study Record

The ***Withdraw SIFTER Study*** activity can be used to withdraw a SIFTER which has a current overall state of either *Pre-Submission* or *Partially Submitted*.

Please Note: Executing this activity cannot be undone.



- Once withdrawn, you will be able to view information previously entered, but you will not be able to submit any of the SIFTER sub-projects.
- **CAUTION:** If the withdrawn SIFTER was created from an existing IRB study, it will not be possible to recreate another SIFTER from the same existing IRB study, therefore this activity should only be used if you are certain that submitting a SIFTER and / or SIFTER amendment will not be needed at any point in the future.

Synchronized Withdrawal of SIFTER with eIRB Study

If the ***Withdraw Submission*** activity in eIRB is executed by the PI, in addition to withdrawing the eIRB study, all sub-projects of the corresponding SIFTER record will also be withdrawn. Once withdrawn, an autogenerated email notification from SIFTER will be sent to process owners for any SIFTER sub-project that had been submitted prior to withdrawal.

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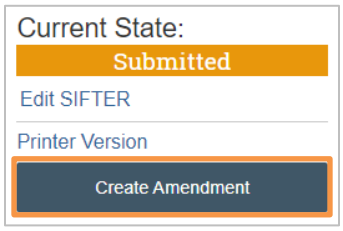
Creating an Amendment for an IRB Study with an Existing SIFTER Record

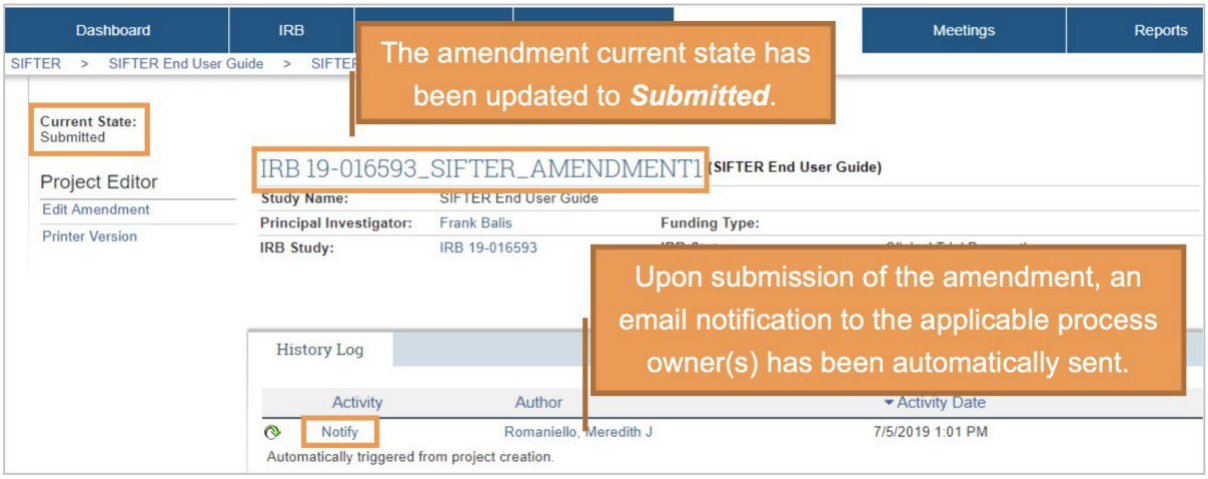
Once a study has been IRB approved / opened to accrual in OnCore, it may be necessary to request changes to the OnCore calendar and / or budget, contract, Epic study build or services being provided by CHPS, Laboratory Services or the Investigational Drug Service. To request these changes, follow the steps below to create a SIFTER Amendment:

1. Click ***Create Amendment*** from the study's SIFTER Workspace.

   Note: If the Create Amendment button is not available within the study's SIFTER Workspace, please email oncore@chop.edu and let us know that you need to submit a SIFTER Amendment.



2. Within the Amendment Information smart form, answer the applicable questions.
3. Click ***OK***. The SIFTER Amendment has been submitted.



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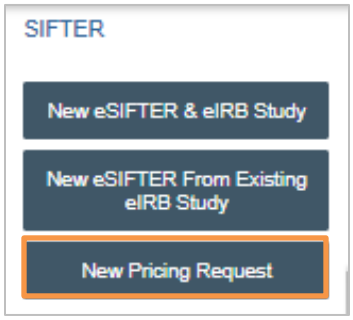
Viewing SIFTER Amendments after Submission

After submission, SIFTER amendments can be accessed / viewed in two different ways:

- Within the ***Project Listing*** of the main SIFTER page, the most recent SIFTER amendment will display.
  - In the Amendment column, click on the ***IRB XX-XXXXXX_SIFTER_AMENDMENTX hyperlink***. Then, under the Project Editor heading, click ***Edit Amendment*** to open / view the amendment.
- Within the ***Amendment*** tab of a study's SIFTER workspace, all SIFTER amendments for the study are displayed.
  - In the Name column, click on the ***Study Name hyperlink***. Then, under the Project Editor heading, click ***Edit Amendment*** to open / view the amendment.

Creating a New Pricing Request

A ***New Pricing Request*** should be created in SIFTER when patient care and / or CHPS pricing is required for an eSPA submission. The information provided will be used by the CTFM Budget Team to **develop the Pricing Request in OnCore**.



Post award, a new SIFTER record, along with the IRB study, should be created / submitted to initiate the process of a full build (protocol, calendar, and budget) in OnCore. If CHPS resources are needed, a new eCHPS submission will also be necessary.

Questions: Please reach out to the CTFM Budget Team at cranalyst@chop.edu.

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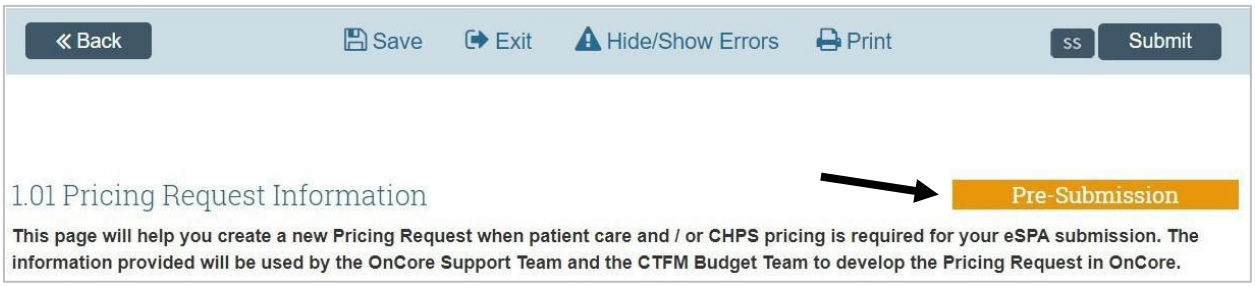
1. Within the ***1.00 Pricing Request Information*** smart form, provide the requested details for Q1 – Q3, then click ***Continue***. A new Pricing Request, with a Current State of Pre- Submission has been created.



2. Within the 1.01 Pricing Request Information smart form, proceed with providing the requested information. **Note**: All questions which reflect a * are required.
   a. If it is not possible to complete data entry all at once, click ***Save***. Then, click ***Exit*** to return to the main workspace for this Pricing Request.
      I. **Note**: This Pricing Request has been assigned a unique ID.
      II. To resume data entry at any time, click ***Edit Pricing Request***.

   b. Upon completion of data entry, click ***Submit***.
      I. Data validation will be facilitated to confirm that all required questions have been answered. If required question(s) remain unanswered, an ***Error / Warning Message***, like the one below will display. Use the ***Jump To hyperlink*** provided to return to the smart form to complete data entry.

II. If data validation returns no errors, within the Submit Pricing Request pop-up, click ***OK***.

3. You will be transferred to the main workspace for this Pricing Request. **Note**: Current State is now ***Submitted***, therefore the smart form can no longer be edited however you can view the submitted smart form by clicking ***View Pricing Request***. The CTFM Budget Team have been notified via email of this submission.

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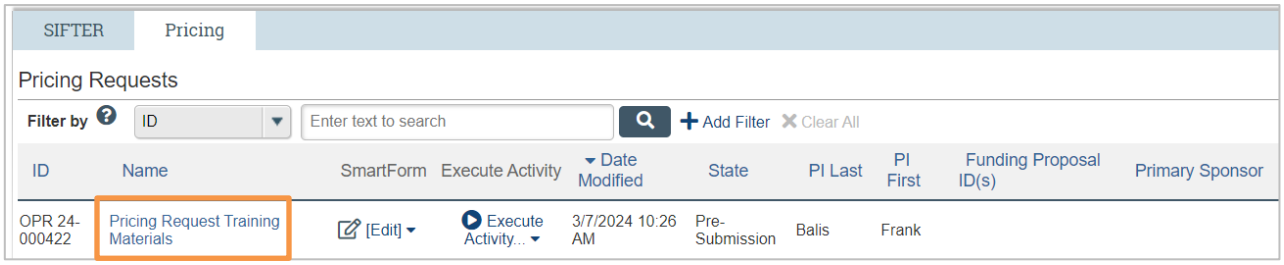
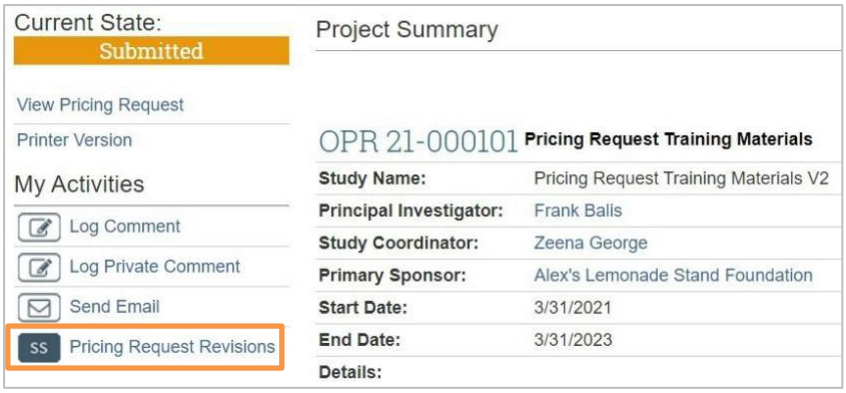
Pricing Request Workspace

Once you have created a new Pricing Request, it can be easily accessed by selecting it from the ***Pricing*** tab > Pricing Requests listing > Name column hyperlink.

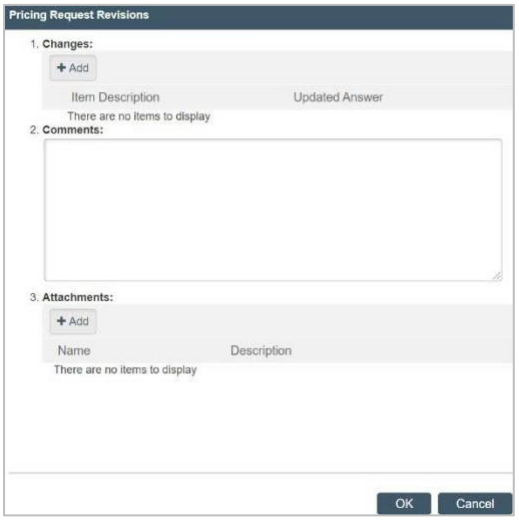


Submitting Pricing Request Revisions

Within the main workspace for each *Submitted* Pricing Request, the ***Pricing Request Revisions activity*** can be used to alert the CTFM Budget Team of changes / new information associated with this Pricing Request.



1. Click ***Pricing Request Revisions.***
2. Use the fields provided to enter the revised / new information for this Pricing Request.
3. Once data entry is complete, click *OK*.
   Note: The ***History Log*** now reflects the utilization of the Pricing Request Revisions activity, including Author and a date / time stamp. The OnCore Support Team and the CTFM Budget Team have been notified via email of these revisions.



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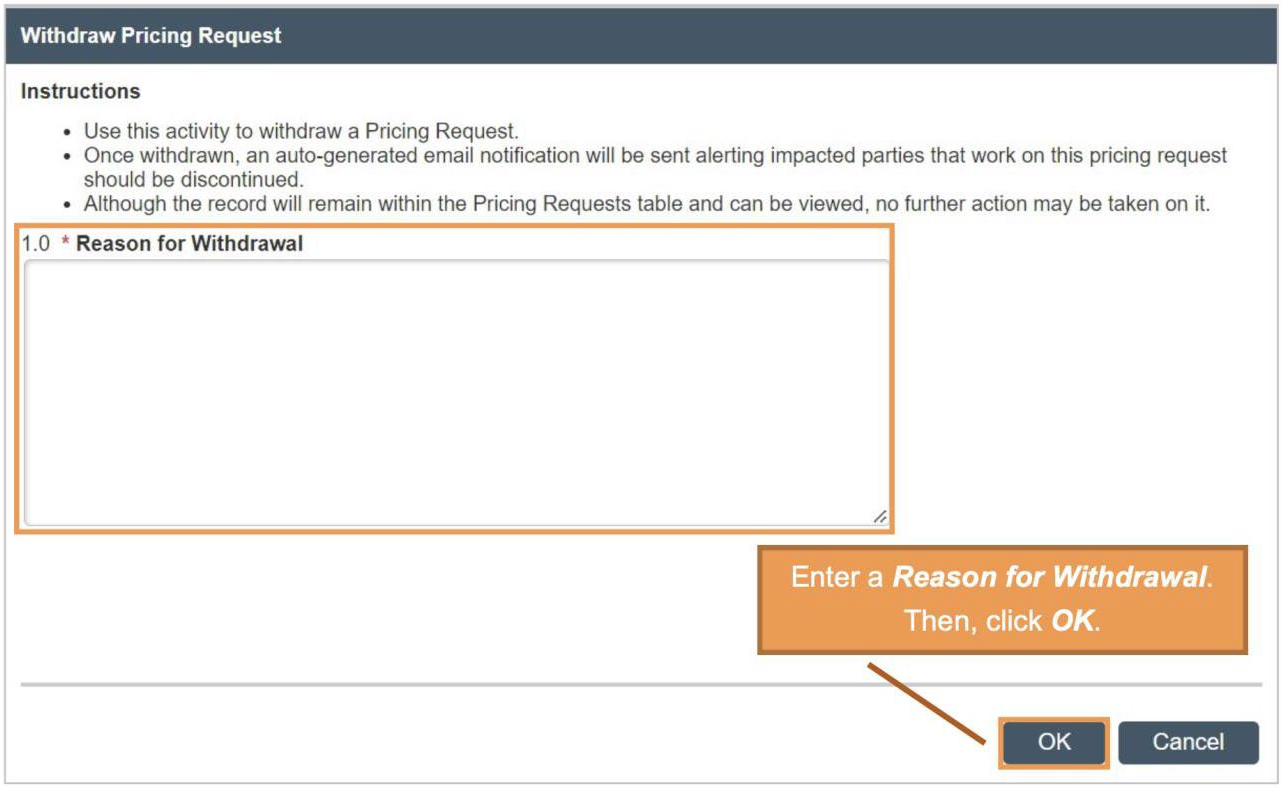
Withdrawing a Pricing Request

The ***Withdraw Pricing Request*** activity can be used to withdraw any Pricing Request record within SIFTER.

Please Note: Executing this activity cannot be undone.



- If Current State = *Pre-Submission* at the time of withdrawal, information previously entered can be viewed, however it is no longer possible to make edits.
- If Current State = *Submitted* at the time of withdrawal, an email notification will be generated to alert the CTFM Budget Team to discontinue work on this Pricing Request. Information previously entered can still be viewed.

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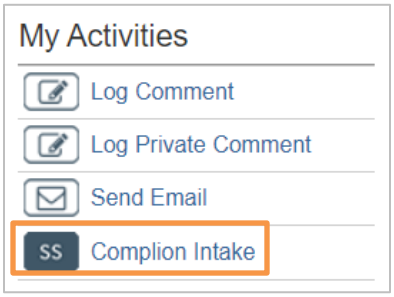
Complion Intake for New Primary Study Binders

Complion is a centralized, electronic application to support remote monitoring, eSignature, and document management. Complion will facilitate digital documentation compliance, address physical document storage constraints, and support information sharing with sponsors and CROs. Click here to learn more about Complion and how it is being used at CHOP. Questions related to the use of Complion can be directed to clinicaltrialsupport@chop.edu.

In SIFTER, the ***Complion Intake*** activity will be used to request a new primary study binder build. The Complion Intake activity will become available within a study's SIFTER workspace after 1.01 OnCore has been submitted.



Upon clicking Complion Intake, the smart form will open in a new window and become available for data entry. When data entry is complete, click OK. Upon clicking OK, the activity is submitted, and SIFTER will generate an email to Clinical Trial Support alerting of the request for a new primary study binder build associated with this IRB No. in Complion.

Note: The Complion Intake activity may only be used one time for each study. After it has been used, it will no longer be available under My Activities, within that study's SIFTER workspace. To request a change in Complion for an existing study, please see below: Request a Change in Complion using SIFTER Amendments.

Use of the Complion Intake activity will be reflected within the History Log.

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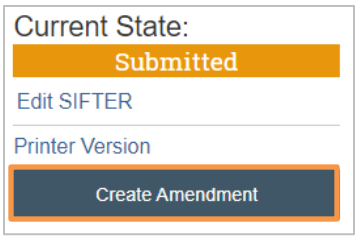
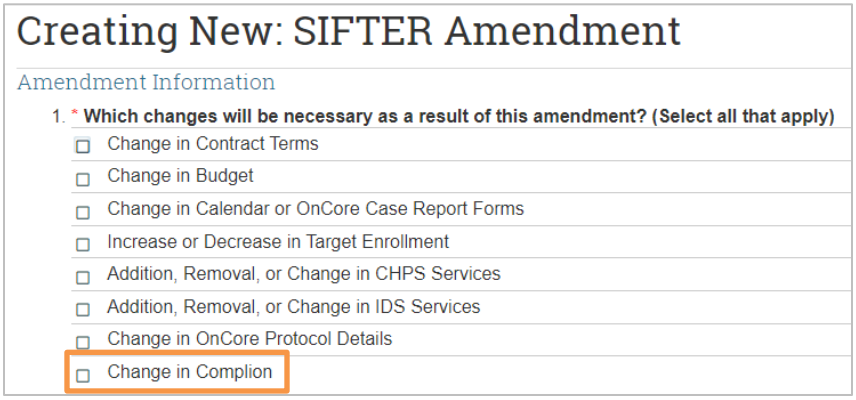
Request a Change in Complion using SIFTER Amendments

Once a primary study binder has been built in Complion, you may request changes by creating a new SIFTER Amendment.

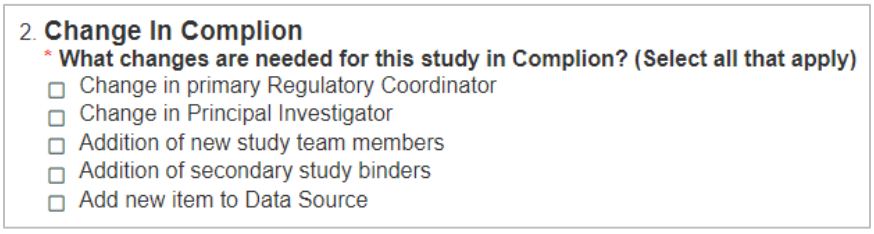
1. Click ***Create Amendment*** from the study's SIFTER Workspace.



2. Within the SIFTER Amendment smart form, select ***Change in Complion***.



3. Select the applicable Complion change type(s) and provide all requested information.



4. When data entry is complete, click ***OK*** in the lower right corner. Upon clicking OK, the Amendment is submitted, and SIFTER will generate an email to Clinical Trial Support alerting of the change request.

Note: See page 13 - Viewing SIFTER Amendments after Submission.