

# 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)
<b>1.01 OnCore</b>	Supports data collection needed to build an OnCore protocol and calendar.	OnCore Support Team
<b>1.02 Budget</b>	Supports data collection needed to develop a budget in OnCore.	CTFM Budget Analysts
<b>1.03 Contracts</b>	Supports data collection needed for the development of a clinical trial agreement.	Clinical Research Contracts Administration (CRCA)
<b>1.04 Drug Information</b>	Supports data collection needed for studies which involve drugs / biologics or placebos.	Investigational Drug Service
<b>1.05 Payments</b>	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
<b>1.06 Epic Study Build</b>	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
<b>1.07 Laboratory</b>	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](mailto:oncore@chop.edu).

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



The screenshot displays the eIRB dashboard interface. At the top left is the eIRB logo. Below it is a navigation bar with tabs for Dashboard, IRB, PeRC, CHPS, and SIFTER. The SIFTER tab is highlighted with an orange border. The main content area shows a folder for Meredith Romaniello with a 'Study Staff' button and a 'My Roles' section listing CHPS Staff Members, Committee Member, and New User. A 'New eIRB Study' button is also visible. Below this is a list of links: IRB Internet, IRB Intranet, OHRP, and FDA Information Sheets. At the bottom, there is a filter section with tabs for Inbox, IRB Studies, In IRB Review, IRB Archived Studies, and CHPS Stud. A search bar is present with a dropdown menu set to 'ID' and a search button.

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### Creating a New SIFTER for Study Start-Up

**Please Note:**  
SIFTER records and IRB studies are always associated with the same IRB No.

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*:

1.00 Introduction

This page will help you to create a new SIFTER Form and its associated IRB Study. Please enter the PI and the Short Title of the new Study, then click the OK button below to proceed.

1. \* Who is the Principal Investigator?

2. Who is the CHOP Study Coordinator?

3. \* Enter the short title (5 words or less) for the Research Protocol:

Exit Save Continue →

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*:

1.00 Introduction

This page will help you to create a new SIFTER Form for an existing IRB Study. Please select the existing study, then click the OK button below to proceed.

1. What IRB Study should be associated to the new SIFTER Form?

Exit Save Continue →

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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*:

The screenshot shows a form titled "1.00 Introduction" with the instruction: "This page will help you to create a new SIFTER Form for an existing IRB Study. Please select the existing study, then click the OK button below to proceed." Below this is a question: "1. What IRB Study should be associated to the new SIFTER Form?" followed by a text input field and a "..." button. An orange callout box points to the "..." button with the instructions: "1. Use the **Browse** button to locate and select an existing IRB study where you are the CHOP Study Coordinator. 2. Click **Continue**." At the bottom right of the form are three buttons: "Exit" (with a refresh icon), "Save" (with a floppy disk icon), and "Continue" (with a right arrow icon).

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](mailto: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.

ID	Name	SmartForm	Execute Activity	Date Modified	State	PI Last	PI First
IRB 23-021374_SIFTER	SIFTER End User Guide	[Edit]	Activity	7/20/2023 11:12 AM	Pre Submission	Aplenc	Richard

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

**Click the *SIFTER* breadcrumb to return to the Project Listing table.**

**Click the *IRB Study* hyperlink to jump to the study's IRB workspace.**

**Current State: Pre Submission** - Represents the overall state of the SIFTER record.

**Edit SIFTER** - Click *Edit SIFTER* to reenter the smart forms to resume data entry.

**Send Email** - Use the *Send Email* activity to correspond with process owners about this study. These emails will be recorded in the History Log.

Subproject	Status
1.01 OnCore:	Pre-Submission
1.02 Budget:	Pre-Submission
1.03 Contracts:	Pre-Submission
1.04 Drug Information:	Unused
1.05 Payment to Subjects and Families:	Pre-Submission
1.06 EPIC Study Build:	Pre-Submission
1.07 Lab:	Pre-Submission

**Represents the status of each sub-project.**

Reflects all activity facilitated by the study team and process owners for this study in SIFTER.

Activity	Author	Activity Date
New SIFTER Created	Romaniello, Meredith J	7/20/2023 11:12 AM

Created new eSIFTER & new eIRB Study.

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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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## Study Intake Form To Expedite Research

### 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.

1.01 OnCore

**Pre-Submission**

This portion of SIFTER captures information required to build a protocol and protocol calendar in OnCore. Questions related to this sub-project can be directed to [oncore@chop.edu](mailto:oncore@chop.edu).

1. Associated CHOP IRB:  
IRB 23-021374
2. \* Who is the Principal Investigator?  
Richard Aplenc
3. Who is the CHOP Study Coordinator?
4. \* Enter the short title (5 words or less) for the Research Protocol:  
SIFTER End User Guide
5. \* State the main objectives of the study. (Three sentences maximum.)  
Objectives

Exit Save **Start OnCore Study** Continue

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.

Error/Warning Messages			Refresh
Message	Field Name	Jump To	
1.01 Q10 is required.	What is the expected accrual duration in months?	1.01 OnCore	
1.01 Q11 is required.	What is the lower accrual goal?	1.01 OnCore	
1.01 Q18 is required.	Who will facilitate Data Monitoring?	1.01 OnCore	

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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.

**Start OnCore Study**


If you would like to Submit the OnCore Study portion of the SIFTER form, press the OK Button below.

---

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

1.01 OnCore

This portion of SIFTER captures information required to build a protocol and protocol calendar in OnCore. Questions related to this sub-project can be directed to [oncore@chop.edu](mailto:oncore@chop.edu).

 **Submitted**

**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.

The screenshot shows the SIFTER web application interface. At the top, there are navigation tabs: Dashboard, IRB, PeRC, CHPS, SIFTER, Meetings, and Reports. Below the tabs, the breadcrumb path is 'SIFTER > SIFTER End User Guide 2'. The main content area is divided into several sections:

- Current State:** Partially Submitted
- Edit SIFTER:** IRB 19-016594\_SIFTER (SIFTER End User Guide 2)
- Printer Version:** SIFTER End User Guide 2
- My Activities:** A list of activities with icons: Log Comment, Log Private Comment, Send Email, Start Budget, Start Contracts, Start Drug Information, Start Payment to Subjects and Families, and Start EPIC Study Build.
- Study Details:** A table with fields: Study Name, Principal Investigator, Study Coordinator, Primary Sponsor, Associated CTA, Associated OnCore, IRB Study, Department / Division, IRB Status, Sponsor Type, and Associated eSPA.
- Subproject Status:** A table with columns: Subproject, Status. Rows include: 1.01 OnCore: Submitted, 1.02 Budget: Pre-Submission, 1.03 Contracts: Pre-Submission, 1.04 Drug Information: Pre-Submission, 1.05 Payment to Subjects and Families: Pre-Submission, 1.06 EPIC Study Build: Pre-Submission.
- History Log:** A table with columns: Activity, Author, Activity Date. A row is shown: Submitted OnCore Study, Romaniello, Meredith J, 7/5/2019 2:40 PM.

The 'Withdraw SIFTER Study' activity is highlighted with an orange box in the 'My Activities' section.

- 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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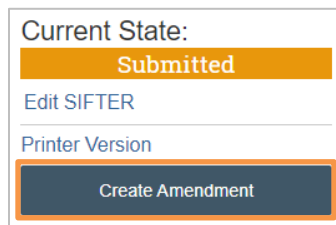
## Study Intake Form To Expedite Research

### 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](mailto:oncore@chop.edu) and let us know that you need to submit a SIFTER Amendment.



Current State:  
**Submitted**  
Edit SIFTER  
Printer Version  
**Create Amendment**

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



The amendment current state has been updated to **Submitted**.

IRB 19-016593\_SIFTER\_AMENDMENT1 (SIFTER End User Guide)

Study Name: SIFTER End User Guide  
Principal Investigator: Frank Ballis  
Funding Type:  
IRB Study: IRB 19-016593

History Log

Activity	Author	Activity Date
Notify	Romaniello, Meredith J	7/5/2019 1:01 PM

Automatically triggered from project creation.

Upon submission of the amendment, an email notification to the applicable process owner(s) has been automatically sent.

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## Study Intake Form To Expedite Research

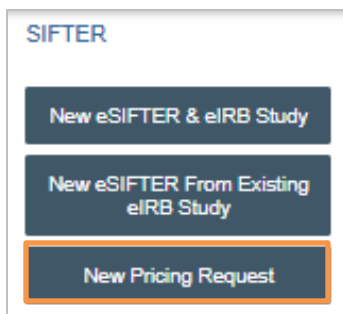
### Viewing SIFTER Amendments after Submission

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](mailto:cranalyst@chop.edu).



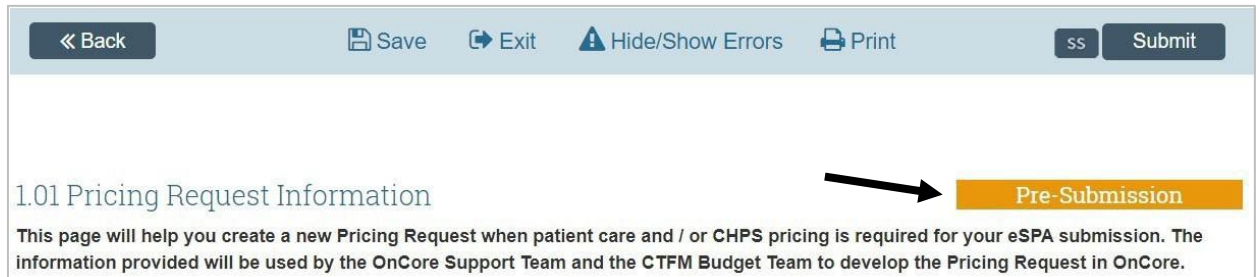
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## Study Intake Form To Expedite Research

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.



1.01 Pricing Request Information **Pre-Submission**

This page will help you create a new Pricing Request when patient care and / or CHPS pricing is required for your eSPA submission. The information provided will be used by the OnCore Support Team and the CTFM Budget Team to develop the Pricing Request in OnCore.

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**.



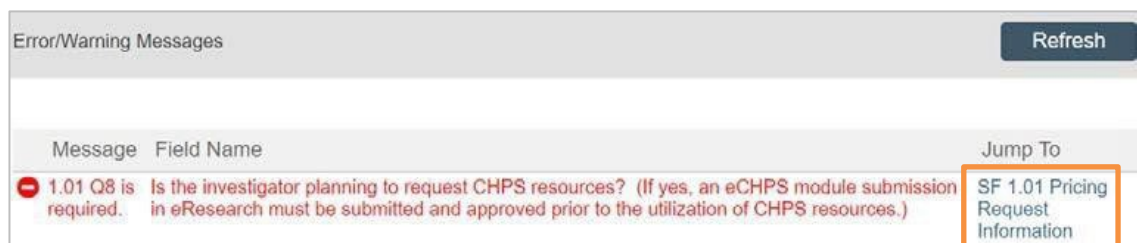
Current State: **Pre-Submission** Project Summary

**Edit Pricing Request** OPR 21-000101

Printer Version

- 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.

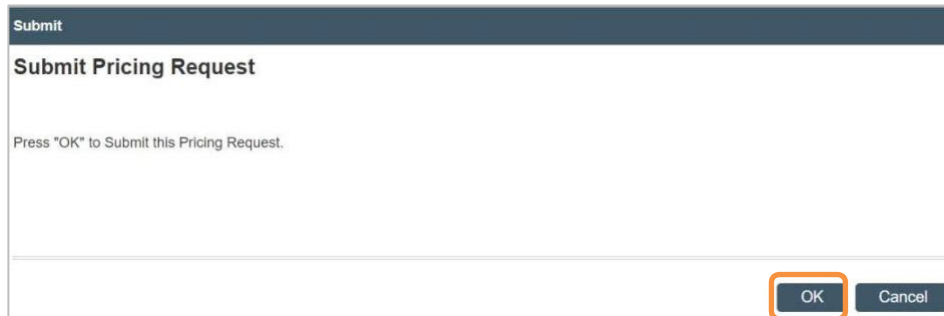


Error/Warning Messages		Refresh
Message	Field Name	Jump To
1.01 Q8 is required.	Is the investigator planning to request CHPS resources? (If yes, an eCHPS module submission in eResearch must be submitted and approved prior to the utilization of CHPS resources.)	<b>SF 1.01 Pricing Request Information</b>

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



The screenshot shows a dialog box titled "Submit Pricing Request" with a dark header bar. Below the title, the text reads "Press 'OK' to Submit this Pricing Request." At the bottom right of the dialog, there are two buttons: "OK" and "Cancel". The "OK" button is highlighted with an orange border.

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.

ID	Name	SmartForm	Execute Activity	Date Modified	State	PI Last	PI First	Funding Proposal ID(s)	Primary Sponsor
OPR 24-000422	Pricing Request Training Materials	[Edit]	Execute Activity...	3/7/2024 10:26 AM	Pre-Submission	Balis	Frank		

### 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.

<b>Current State:</b> Submitted	<b>Project Summary</b>
View Pricing Request	OPR 21-000101 <b>Pricing Request Training Materials</b>
Printer Version	<b>Study Name:</b> Pricing Request Training Materials V2
<b>My Activities</b>	<b>Principal Investigator:</b> Frank Balis
[Log Comment]	<b>Study Coordinator:</b> Zeena George
[Log Private Comment]	<b>Primary Sponsor:</b> Alex's Lemonade Stand Foundation
[Send Email]	<b>Start Date:</b> 3/31/2021
<b>SS Pricing Request Revisions</b>	<b>End Date:</b> 3/31/2023
	<b>Details:</b>

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.

**Pricing Request Revisions**

1. **Changes:**

Item Description	Updated Answer
There are no items to display	

2. **Comments:**

3. **Attachments:**

Name	Description
There are no items to display	

OK Cancel



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
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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.

My Activities	
	Log Comment
	Log Private Comment
	Send Email
	Pricing Request Revisions
	Withdraw Pricing Request

#### Withdraw Pricing Request

**Instructions**

- Use this activity to withdraw a Pricing Request.
- Once withdrawn, an auto-generated email notification will be sent alerting impacted parties that work on this pricing request should be discontinued.
- Although the record will remain within the Pricing Requests table and can be viewed, no further action may be taken on it.

1.0 \* Reason for Withdrawal

Enter a **Reason for Withdrawal**.  
Then, click **OK**.

OK Cancel

- 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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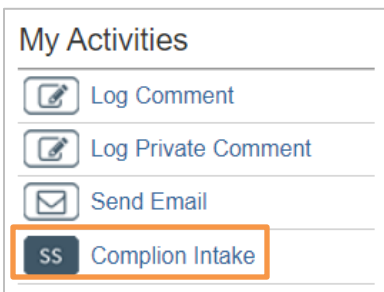
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### Complion Intake for New Primary Study Binders

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](mailto: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.

History Log		Amendments	
Activity	Author	Activity Date	
Complion Intake	Romaniello, Meredith J	3/7/2024 11:34 AM	
Binder Type: Industry Sponsored Study Binder			
Primary Regulatory Coordinator: Meredith Romaniello			



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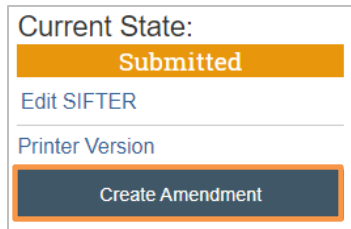
# End User Guide: SIFTER

## Study Intake Form To Expedite Research

### Request a Change in Complion using SIFTER Amendments

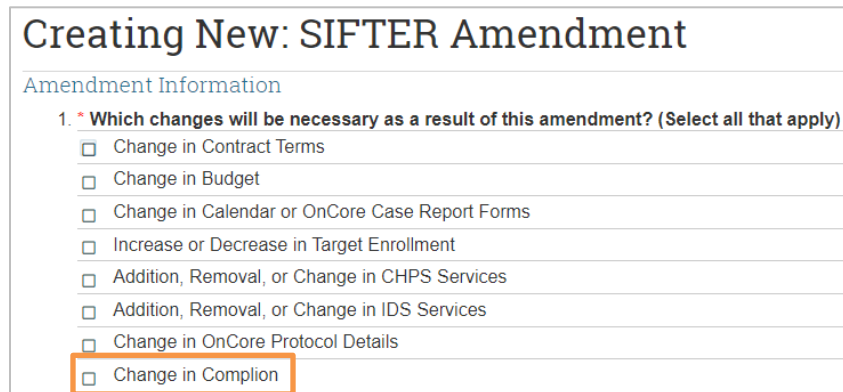
Once a primary study binder has been built in Complion, you may request changes by creating a new SIFTER Amendment.

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



Current State:  
**Submitted**  
Edit SIFTER  
Printer Version  
**Create Amendment**

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



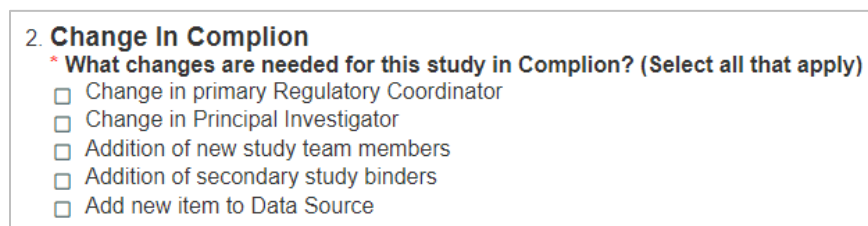
Creating New: SIFTER Amendment

Amendment Information

1. \* **Which changes will be necessary as a result of this amendment? (Select all that apply)**

- Change in Contract Terms
- Change in Budget
- Change in Calendar or OnCore Case Report Forms
- Increase or Decrease in Target Enrollment
- Addition, Removal, or Change in CHPS Services
- Addition, Removal, or Change in IDS Services
- Change in OnCore Protocol Details
- Change in Complion

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



2. **Change In Complion**

\* **What changes are needed for this study in Complion? (Select all that apply)**

- Change in primary Regulatory Coordinator
- Change in Principal Investigator
- Addition of new study team members
- Addition of secondary study binders
- Add new item to Data Source

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.



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