

CHOP's IRB Portal for Relying Institutions Continuing Review

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Create the Continuing Review Application: CHOP Study Team

- At least 30 days prior to the expiration date the CHOP Study Team should create and submit in eIRB the Continuing Review for the study.
- Encourage each Relying Institution to also complete the continuing review application for their participation (see instructions in this document).

Section 3.02 sIRB Continuing Review

- An additional section of the application will be required.
- The investigators who have been approved by CHOP should be listed along with the status of their continuing review application.

3.02 sIRB Continuing Review VIEWID627D0A3F1AE61

1.0 Since CHOP is the reviewing IRB, the CHOP PI is responsible for ensuring that all sites have their continuing review/closure materials submitted prior to expiration. Below is a list of the sites (with executed agreements) for which CHOP is the reviewing IRB. If there is an extenuating circumstance why a continuing review/closure cannot be submitted by a specific site, an exception can be requested.

Update	Relying Institution	Site PI	CR Status	Request Exception
<input type="checkbox"/>	Emory University School of Medicine		Not Submitted	no
<input type="checkbox"/>			Not Submitted	no
<input type="checkbox"/>	Cincinnati Children's Hospital Medical Center		Not Submitted	no
<input type="checkbox"/>	Johns Hopkins University School of Medicine		Not Submitted	no
<input type="checkbox"/>	Children's Mercy		Not Submitted	no
<input type="checkbox"/>	Duke University Health System		Not Submitted	no
<input type="checkbox"/>	Indiana University		Not Submitted	no

2.0 If an exception is requested for any site, please clarify why the site's continuing review/closure will not be submitted prior to expiration (e.g. site is permanently closed):

Section 3.02 sIRB Continuing Review – Exception from Current CR Review

- Select ‘Update’ to request an exception for a specific Relying Institution. Only IRB approved Relying Institutions will be included in the list in Section 3.02 (Q1.0).
- If the Relying Institution is not able to submit the required Continuing Review (e.g. submitting a closure), indicate that an exception is requested. This will allow the investigator to submit the Continuing Review for the other institutions and CHOP.

The screenshot displays the sIRB Continuing Review interface. At the top, there are navigation buttons: Back, Save, Exit, Hide/Show Errors, Print, Jump To, and Continue. The main content area is titled "3.02 sIRB Continuing Review" and includes a sub-section "1.0" with instructions: "Since CHOP is the reviewing IRB, the CHOP PI is responsible for ensuring that all sites have their continuing review/closure materials submitted prior to expiration. Below is a list of the sites (with executed agreements) for which CHOP is the reviewing IRB. If there is an extenuating circumstance why a continuing review/closure cannot be submitted by a specific site, an exception can be requested."

Relying Institution	Site PI	CR Status	Request Exception
Emory University School of Medicine		Not Submitted	no
		Not Submitted	no
		Not Submitted	no
		Not Submitted	no
		Not Submitted	no
		Not Submitted	no
		Not Submitted	no

A modal dialog titled "Edit sIRB Relying Study CR Status-Exception" is open, showing the following details:

- Relying Study: IRB 18-015440_RS16
- Relying CR: CR State: Not Submitted
- * Would you like to request an exception?
 - Yes
 - No
 - [Clear](#)

At the bottom of the dialog are "OK" and "Cancel" buttons. Below the dialog, section "2.0" is partially visible with the text "If an exception is" and a "no" selection.

Missing Relying Institution Continuing Reviews or Exceptions

- If at least one Relying Institution has not submitted the required Continuing Review an error will result in eIRB.
- Return to Section 3.02 to request an exception.

Submit Continuing Review

Could not execute the Submit Continuing Review activity due to one or more errors:
See below for more information.

- All sIRB Continuing Reviews must either be Submitted or have an exception.

Use this form to submit your **completed continuing review**. If you click **ok**, you are no longer able to modify the continuing review. You will be notified about the review result by email.

If you are not ready for submission, click **cancel**.

* **Do you want this study to be posted on CHOP's public website?**
 Yes No [Clear](#)

If Yes, you must select up to three (3) Keywords to be associated with this study:

Keyword

There are no items to display

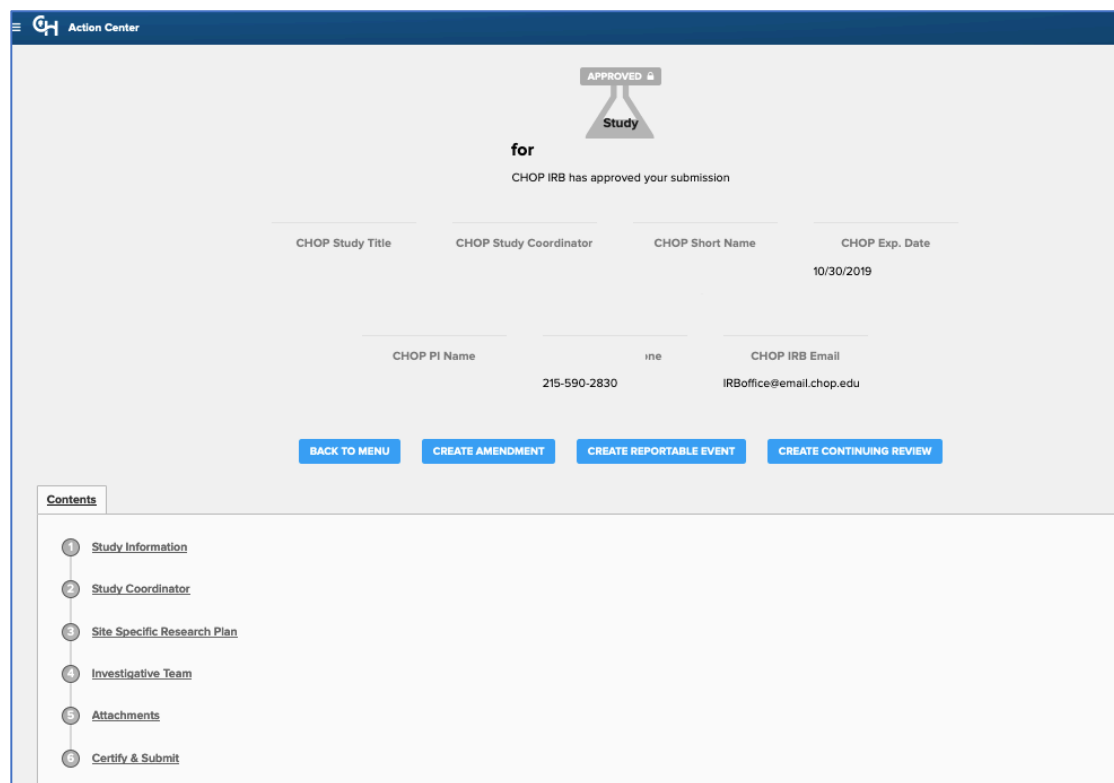
Study Contact Phone Number (required if posting on CHOP's public website):

Study Contact Email:

OK Cancel

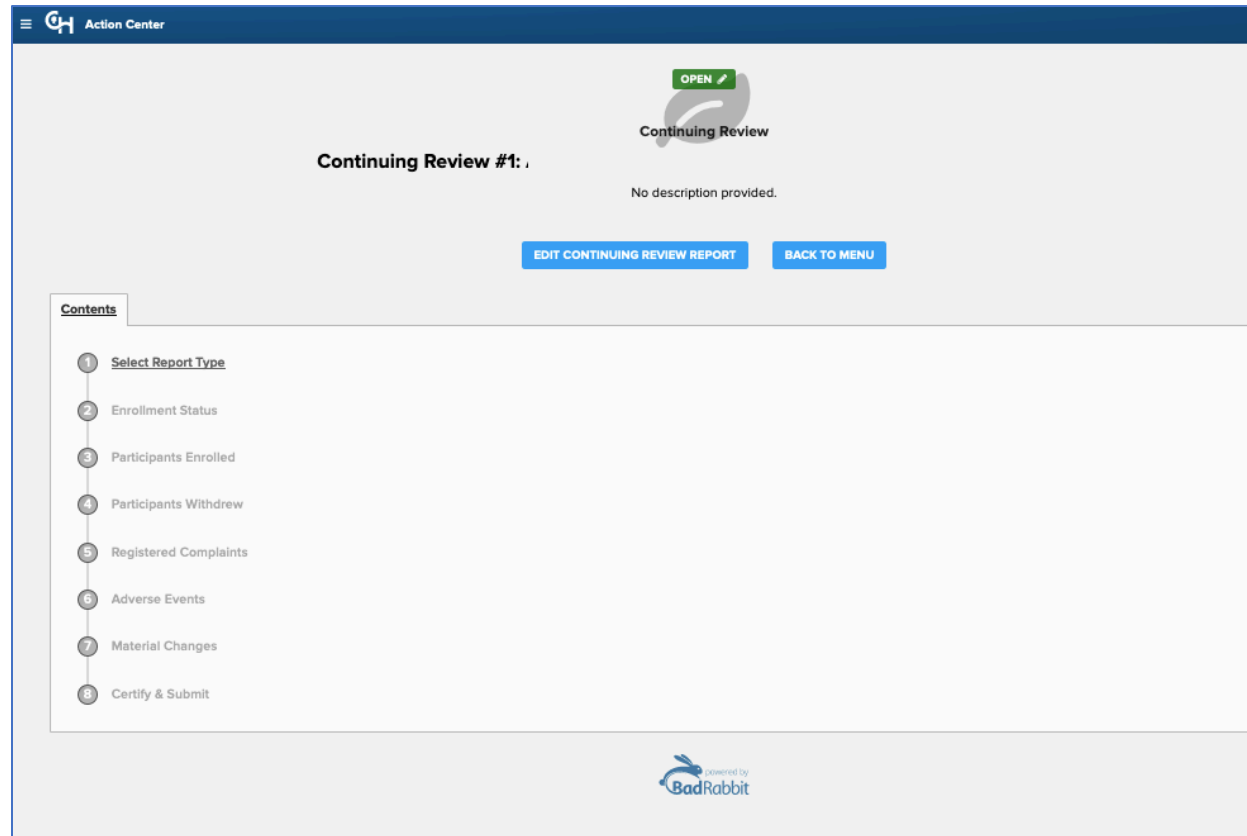
Create the Continuing Review Application: Relying Institution

- Log into the CHOP IRB Portal for Relying Institutions using the same username and password used at the time of initial review by the CHOP IRB.
- The Relying Investigator should select 'Create Continuing Review' in the CHOP IRB action center.
- This report should be submitted at least 30 days prior to IRB approval expiration.



Edit the Continuing Review Application

- Select “Edit Continuing Review Report” to begin the application.



Type of Continuing Review Application

- Select the type of report:
 - Continuing Review – continue human subjects research
 - Closure Report – all human subjects research completed at the Relying Institution

No description provided.

[EDIT CONTINUING REVIEW REPORT](#) [BACK TO MENU](#)

Contents

1 **Select Report Type**

***Select Report Type**

Continuing Review Report

Closure Report

[CONTINUE](#) [EXIT](#)

2 Enrollment Status

3 Participants Enrolled

4 Participants Withdrew

5 Registered Complaints

6 Adverse Events

7 Material Changes

8 Certify & Submit

Enrollment Status

- Indicate for the Relying Institution the status of enrollment:

The screenshot shows a web application interface for "Enrollment Status". At the top, there are two buttons: "EDIT CONTINUING REVIEW REPORT" and "BACK TO MENU". Below these is a "Contents" tab. A vertical progress indicator on the left shows steps 1 through 8. Step 1, "Select Report Type", is completed with a checkmark. Step 2, "Enrollment Status", is the current step and is highlighted with a blue circle. The main content area contains a section titled "Enrollment Status" with three radio button options: "Enrolling Subjects" (selected), "Enrollment Closed, subjects may be re-consented", and "Enrollment Closed". At the bottom of this section are three buttons: "CONTINUE", "BACK", and "EXIT". The remaining steps in the progress indicator are: 3. Participants Enrolled, 4. Participants Withdrew, 5. Registered Complaints, 6. Adverse Events, 7. Material Changes, and 8. Certify & Submit.

Number of Subjects Enrolled

- Indicate for the Relying Institution the number of subjects enrolled in the research since the last review by the CHOP IRB.

No description provided.

[EDIT CONTINUING REVIEW REPORT](#) [BACK TO MENU](#)

Contents

- 1 [Select Report Type](#)
- 2 [Enrollment Status](#)
- 3 **Participants Enrolled**
- 4 [Participants Withdrew](#)
- 5 [Registered Complaints](#)
- 6 [Adverse Events](#)
- 7 [Material Changes](#)
- 8 [Certify & Submit](#)

* # Subjects Enrolled since the last IRB (Initial or Continuing) review:

[CONTINUE](#) [BACK](#) [EXIT](#)

Number of Subjects Withdrawn

- Indicate for the Relying Institution the number of subjects who have withdrawn from the study and the reasons for the withdrawal(s).

The screenshot shows a web interface for reporting study data. At the top, there are two buttons: "EDIT CONTINUING REVIEW REPORT" and "BACK TO MENU". On the left, a "Contents" sidebar lists several sections: "Select Report Type", "Enrollment Status", "Participants Enrolled", "Participants Withdrew" (which is highlighted with a blue circle and the number 4), "Registered Complaints", and "Adverse Events". The main content area contains two questions:

*Since the last continuing review, did any subjects at your site withdraw from the study or were any withdrawn by the investigator? Yes No

*Provide the number of withdrawn subjects and the reasons for the withdrawal(s)

Below the second question is a large text input field. At the bottom of the form are three buttons: "CONTINUE", "BACK", and "EXIT".

Subject Complaints

- Indicate for the Relying Institution any subject complaints about the research or study personnel.

[EDIT CONTINUING REVIEW REPORT](#) [BACK TO MENU](#)

Contents

- ✓ [Select Report Type](#)
- ✓ [Enrollment Status](#)
- ✓ [Participants Enrolled](#)
- ✓ [Participants Withdrew](#)
- 5** [Registered Complaints](#)
- 6 [Adverse Events](#)
- 7 [Material Changes](#)
- 8 [Certify & Submit](#)

5 Registered Complaints

*** Since the last continuing review, have subjects at your site registered any complaints about the research or study personnel?**

[CONTINUE](#) [BACK](#) [EXIT](#)

Adverse Events/Unanticipated Problem Involving Risks to Subjects or Others

- Indicate for the Relying Institution any Adverse Events/Unanticipated Problem Involving Risks to Subjects or Others that have not been previously reported to the CHOP IRB.

The screenshot shows a web interface for reporting adverse events. On the left, a vertical navigation menu contains several items: 'Enrollment Status', 'Participants Enrolled', 'Participants Withdrew', 'Registered Complaints', 'Adverse Events' (which is highlighted with a blue circle and the number 5), 'Material Changes', and 'Certify & Submit'. The main content area is titled 'Adverse Events' and contains a text box with the following instructions: 'Provide (or attach) a summary of any noteworthy adverse events (including any that occurred with an unexpected frequency or severity), protocol deviations, or other study-related issues that occurred at your site and did not meet the criteria for prompt reporting to the CHOP IRB (e.g. Unanticipated Problems involving risk to subjects or others or non-compliance)'. To the right of this text is a large empty rectangular box for input. Below the text box, there is a section for file uploads with the text 'Attach a text file' and 'No attachments.' and an 'UPLOAD' button. At the bottom of the form, there are three buttons: 'CONTINUE', 'BACK', and 'EXIT'. At the bottom left of the page, there are two more items in the navigation menu: 'Material Changes' and 'Certify & Submit'.

Material Changes

- Indicate for the Relying Institution if there have been any material changes that have not been previously submitted to the CHOP IRB.
- Include details of the changes.

The screenshot shows a web interface for editing a continuing review report. At the top, there are two buttons: "EDIT CONTINUING REVIEW REPORT" and "BACK TO MENU". Below these is a "Contents" tab with a vertical list of menu items: "Select Report Type", "Enrollment Status", "Participants Enrolled", "Participants Withdrew", "Registered Complaints", "Adverse Events", and "Material Changes". The "Material Changes" item is highlighted with a blue circle containing the number 7. The main content area contains a text prompt: "*Have there been any material changes to the study information in the Single IRB Portal, which were not previously reported to the CHOP IRB? If so, briefly outline the nature of these changes." To the right of the text is a large, empty text input box. Below the input box are three buttons: "CONTINUE", "BACK", and "EXIT". At the bottom left of the interface, there is a button labeled "8 Certify & Submit".

Confirmation and Submission by the Relying Investigator

- Confirm and submit the Continuing Review application.

Participants Enrolled

Participants Withdrew

Registered Complaints

Adverse Events

Material Changes

8 Certify & Submit

Confirm the following:

- All information submitted to the CHOP IRB is current and accurate.
- All Unanticipated Problems that met reporting criteria were submitted to the CHOP IRB as Reportable Events. (CHOP IRB Policies are available at <https://irb.research.chop.edu/policies>)

* Certification By submitting this form I certify that, to the best of my knowledge, the information supplied is complete and correct.

Attach any other documents pertaining to this continuing review submission. (e.g. cover letter, or monitoring report). *No attachments.*

UPLOAD

SUBMIT CONTINUING REVIEW REPORT BACK