

# Define a Consent Revision

The purpose of this guide is to illustrate the steps required to define a new consent revision.

Examples of how a consent could be revised:

- PI and/or Research Coordinator contact information updates
- Continuing Review
- Changes to the consent definition

In each of these cases, a new consent document is defined with a new effective start date and end date. These revised consents will need to be defined in Consent Management.

## Definitions

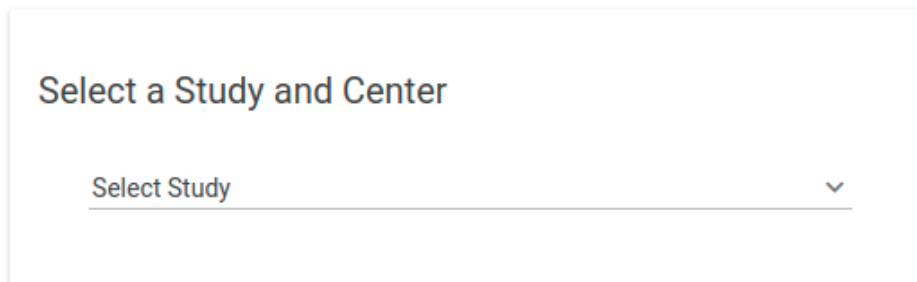
Parental Permission: Type of form (or signatory) used when the Parent / Legal Authorized Representative is providing consent on behalf of a participant. The signatory is the Parent / Legal Authorized Representative.

Assent: Type of form (or signatory) used when a participant is not at the age of majority, but is also old enough to participate in the consenting process. This is typically at age 11. A simplified version of the consent document is made available to the participant for them to provide their assent to. Legal consent is still obtained by the Parent / Legal Authorized Representative.

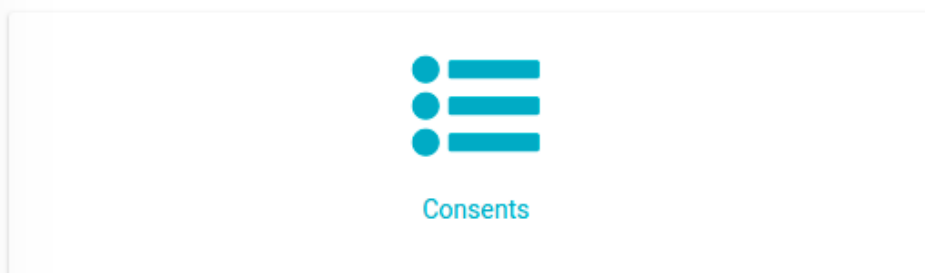
Consent: Type of form (or signatory) used when the participant is providing consent to participate on their own behalf.

## Step-by-step guide

1. Login to the Consent Management System: <https://econsent.research.cchmc.org>
2. Select your Study and Center

A screenshot of a web interface showing a dropdown menu titled "Select a Study and Center". Below the title is a search bar with the placeholder text "Select Study" and a downward arrow icon on the right.

- a.
  - b. Note #1: If you have access to only 1 Study, then it will be preselected for you
  - c. Note #2: If you have access to only 1 Study and 1 Center and you are **not** a Study Administrator, then you will be directed straight into your study
3. Click on the Consents button

A screenshot of a web interface showing a button labeled "Consents". The button is blue with white text and has three horizontal lines above it.

- a.
4. In the Consents page, you will see a list of consents that are currently active (by default).

Demo.Consent Version 5 01/01/2019 - 01/01/2050	New Revision	Parental Permission	Yes	0 - 10	17	👁
	Edit	Assent	Yes	11 - 17	17	👁
	Delete	Consent	Yes	18		👁

- a.
- b. If you do not see any consents, or not the consents that you were expecting, it could be because the consent has expired. Click on the "Yes" button to flip the Active Consents Only flag to "No" and then click on the Search button.

A screenshot of a web interface showing a toggle switch labeled "Active Consents Only". The switch is currently set to "Yes" (green button) and can be flipped to "No" (blue button).

- c.

<b>Demo.Consent</b> Version 5 01/01/2019 - 01/01/2050	New Revision	Parental Permission	Yes	0 - 10	17	
	Edit	Assent	Yes	11 - 17	17	
	Delete	Consent	Yes	18		
<b>Demo.Consent</b> Version 4 01/01/2018 - 01/01/2050		Parental Permission	Inactive as of 2019-01-01	0 - 10	17	
		Assent	Inactive as of 2019-01-01	11 - 17	17	
		Consent	Inactive as of 2019-01-01	18		
<b>Demo.Consent</b> Version 3 01/01/2017 - 01/01/2050		Parental Permission	Inactive as of 2018-01-01	0 - 10	17	
		Assent	Inactive as of 2018-01-01	11 - 17	17	
		Consent	Inactive as of 2018-01-01	18		

d.

5. Look for the most recent version of the consent, and then click on the "New Revision" button

New Revision

a.

6. Select which signatories (documents) to revise

- a. This is the start of the consent wizard. The idea here is to identify what signatories are affected in this update. In some cases, only 1 document (or signatory) gets updated. Generally, in continuing review, all documents get updated. Another thing to point out here. Not all studies require all signatories. Some studies are dealing with only minor populations and would therefore target Parental Permission and Assent. Some studies target adult population, and therefore would target Consent. Just be sure to select appropriate signatories based on your study definition.

### Consent Options

Based on the options selected the wizard will capture more information in the following steps.

Note: The questions and documents in the consents that are not selected in this new revision will be carried over from the previous revision.

Will the legally authorized representative participate in research?

Yes >> No <<

☒ Parental Permission  
☒ Assent  
☒ Consent

Next

b.

- c. Click "Next" button

7. Fill in the new effective dates for the consent and click Next button (no other values **typically** change in a Revision)

- a. Note: Currently an end date is required. If there is no end date for the consent document, then our recommendation is to supply a far-future date. Ex: 01/01/2050

## Consent Information

Note: Only the consents selected in the previous screen are editable.

Consent Name

Demo.Consent

Effective Dates ⓘ

Start Date

End Date

## Parental Permission

Enrollment Ages ⓘ

From

To

Maximum Age ⓘ

Age

01

10

17

## Assent

Enrollment Ages ⓘ

From

To

Maximum Age ⓘ

Age

11

17

17

## Consent

Enrollment Ages ⓘ

From

To

Maximum Age ⓘ

Age

18

◀ Back

▶ Next

b.

c. Click "Next" button

8. Review and update the consent questions based on the consent document. Again, typically questions do not change, but sometimes they do. Questions should map directly to questions in the consent document/form that signatories would have to reply to. They are typically checkboxes.

a. To remove a question, click on the delete icon:


## Consent Questions

During this step you can add additional consent questions. The order of the questions for a consent can be changed anytime by dragging and dropping a question to the desired position.

Note: Questions can be removed/added only to the consents selected in the first screen.

New Question

## Parental Permission

Question	Order	
I agree to be contacted for future research	1	

i.

b. To add a question, click the "New Question" button:

## Consent Questions

During this step you can add additional consent questions. The order of the questions for a consent can be changed anytime by dragging and dropping a question to the desired position.

Note: Questions can be removed/added only to the consents selected in the first screen.

### Which signatories are shown this question? \*

☒ Parental Permission ☒ Assent ☒ Consent

**B I U S**

I agree to be contacted for future research

### Is Answer mandatory \*

☐ Yes ☒ No

 Cancel

 Save

- i.
  - ii. Some questions will exist for some signatories (forms), but not all. Select which signatories the question is applicable to.
  - iii. Enter the question. All questions should be in the form of a Yes/No question. If the question does not exist as a Yes/No question on the consent document, then the question will need to be translated into a Yes/No question.
  - iv. If by answering "No" to the question, the applicant is no longer eligible to participate, select "Yes" for "Is Answer mandatory".
  - v. Click "Save" and you will see the question added to all selected signatories.
  - c. If questions need to be reordered, click on the question and drag it up or down within its group of questions. Ordering is separate for each signatory, so if you reorder one, you will more than likely need to reorder the others.
  - d. Click "Next" button
9. Upload the consent document(s)

## Consent Documents

During this step you add the documents that are associated with each signatory. The order of the documents can be changed anytime by dragging and dropping a document to the desired position.

Note: Documents can be added only to the consents selected in the first screen.

New Document

### Parental Permission

Document

No records found.

### Assent

Document

No records found.

### Consent

Document

No records found.

 Back

 Next

- a.
- b. Click on the "New Document" button

Which signatories are shown this document? \*

☐ Parental Permission ☐ Assent ☐ Consent

+ Choose



Cancel

- i.
  - ii. Select which signatories are included in the consent document.
  - iii. Click the Choose button and select a file to upload.
  - c. Click "Next" button
10. Review the information provided

### Review

**Form Name** Demo.Consent

**Effective Dates** 06/1/2019 - 01/1/2050

Signatory	Enrollment Age Range	Maximum Age
Parental Permission	0 - 10	17
Assent	11 - 17	17
Consent	18	

Finish

- a.
  - b. If all information is correct, click the "Finish" button.
11. You should now be directed back to the Consents homepage. The consent you created should now be listed and active.

## Related articles

- [Define a Consent Revision](#)