

After it has been determined that the affiliate site is engaged, research activities can be conducted at the affiliate site and all regulatory requirements have been met with the Reviewing IRB, the UChicago study team should update the acknowledged CIRB form in AURA IRB.

From the study's main page, click on the Update CIRB Activity button to unlock the application.

Click on edit the SmartForm.

Edit the sections below as applicable.

- 1.1 Outside IRB of Record Question 2: If the Reviewing IRB required the affiliate site to sign a reliance agreement, attach the signed agreement to question 2.
- 1.1 Outside IRB of Record Question 4: If the Reviewing IRB required approval for the affiliate site, attach the IRB approval for the affiliate site.
- 1.1 Outside IRB of Record Question 5: If the Reviewing IRB required revisions to the local context form, attach the revised or new LCF.
- 2.4 Study Locations: Select the affiliate site locations where the research will occur.
- 11.1 Recruitment Question 2: If the medical record at the affiliate site will be utilized for recruitment of participants, please also select: Covered Entity outside of the UChicago.
- 12.2 Data Confidentiality: If any data, electronic or paper will be stored at the affiliate site, please describe in 12.2 Question 1a.
- 14.1 Protected Health Information Question 1a: Revise the response to select the option for Covered Entity outside of the UChicago.
- 16.0 Consent and Assent Documents: Attach the revised consent approved by the IRB of record. This may be a separate consent for use only at the affiliate site or a single consent to be used at either UCM or Affiliate Site. If there is a separate consent for the affiliate site, please clearly label the consents.

For studies relying on the NCI IRB please also include the following:

- 16.0 Consent and Assent: Attach the AdventHealth General HIPAA authorization form.
- *If the reviewing IRB does not provide HIPAA determinations, the AdventHealth General HIPAA Authorization should be included.
- 17.0 Supporting Documents Question 2: Attach the covered study addendum and master agreement between AdventHealth and UCM.

When submitting the changes, the AURA form will ask you to provide a short description of the changes, state that the AURA CIRB form has been updated to include the addition of an affiliate site. Applicable sections of the AURA form have been revised to describe the research activities being conducted at the affiliate site.

After updating the SmartForm, return the study's main page and click on the CIRB Updates Completed button.

After updating the CIRB form to include the affiliate site, a personnel amendment should be submitted to include the affiliate site staff as research personnel.

If Affiliate Site is not engaged:

Study teams should work with the UCM IRB and Research Integration to determine whether the affiliate site is engaged in the research. Once it has been determined they are not engaged, the CIRB form in AURA IRB should be updated to reflect the affiliate site.

From the study's main page, click on the Update CIRB Activity button to unlock the application.

Click on edit the SmartForm.

Edit the sections below.

- 2.4.1 Outside Sites Question 1: Revise the response to check the option for yes and include the affiliate site where research activities are occurring.
- 17.0 Supporting Documents Question 2: Correspondence from the Reviewing IRB that documents they are aware of the addition of the performance affiliate site and that all required actions through the Reviewing IRB have been completed. Additionally, for studies adding Advent Health, the covered study addendum should be attached.

When submitting the changes, the AURA form will ask you to provide a short description of the changes, state that the AURA CIRB form has been updated to include the addition of a non-engaged affiliate site. Applicable sections of the AURA form have been revised to describe the activities being conducted at the affiliate site.

After updating the SmartForm, return the study home page and click on the CIRB Updates Completed button.