

**Description:** Once a protocol has gone through its entire life cycle (i.e. no more subjects are in treatment/follow-up and the IRB has issued a closure letter), you will need to close out the study in OnCore.

**Audience:** Study team members who are responsible for documenting IRB reviews and closing out studies

## DOCUMENT THE IRB STUDY CLOSURE

1. Navigate to **Menu > Protocols > PC Console**.
2. [Find your study](#) using the **Select Protocol** search field.
3. Using the vertical menu bar, navigate to **Reviews > IRB**.
4. Click the **[Add]** button.

Review Date	Submit Date	IRB Committee	Review Reason	Review Type	Review No.	Action	Action Date	Expiration Date	Delete?
11/07/2016	11/07/2016	WIRB	Revision	Full		Approved	11/07/2016	11/07/2019	<input type="checkbox"/>
Communications									
Details (Type / Amendment No / Received Date / Description / Version Date)									
Informed Consent 11/07/2016 TX Consent V2 11/07/2016									
10/15/2016	10/15/2016	WIRB	Initial Review	Full		Approved	10/15/2016	10/15/2019	<input type="checkbox"/>
Communications									
Details (Type / Amendment No / Received Date / Description / Version Date)									
Informed Consent 10/15/2016 TX Consent V1 10/15/2016									

5. In the **Review Date** field, type in the date of the IRB Review, using the following date format MM/DD/YYYY and then make sure the date is entered by either clicking on the date hyperlink in the resulting drop-down list **OR** hit the “Tab” key on your keyboard.



**IMPORTANT:** If the Review Date is not properly entered, OnCore will NOT retain the Review Date when the review record is submitted/closed. There are several areas of OnCore functionality that rely on properly entered review dates; For example, UF will not be able to invoice for close out fees if the **Review Date** is blank.

6. Continue by entering the following required fields:
  - Submit Date
  - Committee
  - Review Reason: **Study Closure**
  - Review Type
  - Action
  - Action Date
  - Expiration Date
7. Click **[Submit]**.
8. Confirm that the **Review Date** appears on this review entry. If not, edit the entry and re-enter the **Review Date** per step 5 above.

## ADD IRB STUDY CLOSURE LETTER

1. If you are not currently in the applicable IRB record, [Find the IRB Review](#) where the closure was approved.
2. Click on the little blue **Edit** hyperlink next to the applicable review line.
3. In the **Details** section at the bottom of the IRB review record, click the **[Add]** button.

Review Information

Review Date: 04/04/2020 | Submit Date: 04/03/2020 | Committee: UF IRB-01 (GNV) | Review Reason: Study Closure | Review Type: Full

Action: Approved | Action Date: 04/03/2020 | Expiration Date: | Review No.:

Summary: 4000 character(s) remaining

Yes Votes: | No Votes: | Abstain Votes: | Institution:

**Details (0)** | Reviewers (0) | Communications (0) | Notes

**Add** | Select Previous Details/Docs

Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
						<input type="checkbox"/>	N/A	<a href="#">Save</a> <a href="#">Cancel</a>

No records found

Submit | Submit and Close | Clear | Close

4. In the detail item row that appears, select the review item from the **Type** drop-down list (e.g. **IRB Approval Letter**).
5. Enter a **Description** for the document (e.g. **IRB Study Closure**).
6. Click the small blue [Save](#) on the far right.

**Details (0)** | Reviewers (0) | Communications (0) | Notes

**Add** | Select Previous Details/Docs

Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
IRB Approval Letter			04/03/2020	IRB Study Closure		<input type="checkbox"/>	N/A	<a href="#">Save</a> <a href="#">Cancel</a>

No records found

This creates a detail line that only describes the document. **You will still need to attach the actual document** (see next steps).

7. Under the detail line you just created, click the blue [File](#) hyperlink.

**Details (1)** | Reviewers (0) | Communications (0) | Notes

**Add** | Select Previous Details/Docs

Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
IRB Approval Letter			04/03/2020	IRB Study Closure		<input type="checkbox"/>	N/A	<input type="checkbox"/>

Attach a [File](#) or URL

8. Click **[Browse]** or **[Choose File]**.
9. Locate the IRB study closure letter on your local computer or network hard drive and select it.
10. Click **[Open]** to upload the file to OnCore.

11. Confirm that you now see the file name next to the **[Choose File]** button.

Details (1) Reviewers (0) Communications (0) Notes

Details Add Select Previous Details/Docs

Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
IRB Approval Letter			04/03/2020	IRB Study Closure		<input type="checkbox"/>	N/A	<input type="checkbox"/>

Attach a File: Choose File **IRB Study Closure.docx** or URL

12. Click **[Submit]** to save this document to this record.

Details (1) Reviewers (0) Communications (0) Notes

Details Add Select Previous Details/Docs

Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
IRB Approval Letter			04/03/2020	IRB Study Closure		<input type="checkbox"/>	N/A	<input type="checkbox"/>

**IRB Study Closure.docx** Release:  Delete:

13. Confirm that you now see a **blue hyperlink** for the document to the left of a **Release** checkbox.

14. Select the **[Release]** checkbox.



*If you miss selecting the **Release** checkbox, the new document will **NOT** show up in document search.*

15. Click **[Submit]**.

## UPDATE THE PROTOCOL STATUS

Once you have the **IRB Study Closure** documented in OnCore, you can mark the study as closed with the IRB. The study **MUST** be in a **Closed to Accrual** status before the IRB Study Closure can be completed.

1. Navigate to **Menu > Protocols > PC Console**.
2. [Find your study](#) using the **Select Protocol** search field.
3. Click the **PC Console > Status** vertical menu.

★ PC Console ?

Protocol No.: OCR33677 Library: Academic Health Center PI: Sevier, Brian, J Sponsor: Amgen Inc.

Protocol Target Accrual: 50 Accrual To Date: 4 Protocol Status: **CLOSED TO ACCRUAL**

RC Total Accrual Goal (Upper): IRB Expiration: 03/31/2020

Select Protocol [Dropdown]

Main Treatment Institution Accrual Status Reviews

Status	Task Lists	ClinicalTrials.gov			
Protocol Status History					
Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
04/03/2020	CLOSED TO ACCRUAL	Other	Accrual goal met		Stamm,Patricia
04/01/2019	OPEN TO ACCRUAL				API,OnCore
04/01/2019	OCR SIGNOFF				API,OnCore
04/01/2019	IRB INITIAL APPROVAL				API,OnCore
02/25/2020	NEW				API,OnCore

Undo Close To Accrual **IRB Study Closure** Terminate Open Update

4. Confirm that the following **REQUIREMENTS** have been met:
  - Protocol Status = **CLOSED TO ACCRUAL** – see [Close to Accrual](#)
  - All participants are in an **OFF STUDY** status
5. Once all the requirements have been met, click the **[IRB Study Closure]** button.
6. Enter the applicable **Status Date**.
7. Click the **[Submit]** button. The Protocol Status will update to "IRB Study Closure". If this study has been interfaced to Epic, then the Epic study status will be changed to **COMPLETED**.
8. Email [OCR-Financials@ahc.ufl.edu](mailto:OCR-Financials@ahc.ufl.edu) and let them know it is time to close the study in UFIRST and myUFL.