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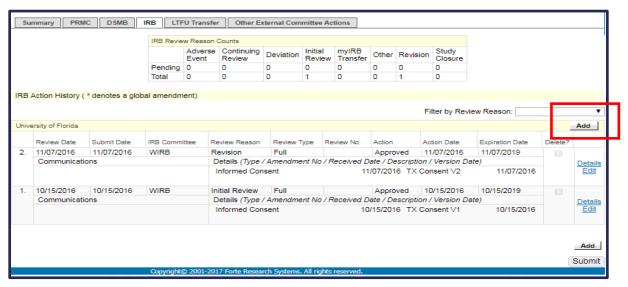
Description: Once a protocol has gone through its entire life cycle (i.e. no more subjects are in treatment/follow-up and the IRB has issued a closure letter), you will need to close out the study in OnCore.

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.

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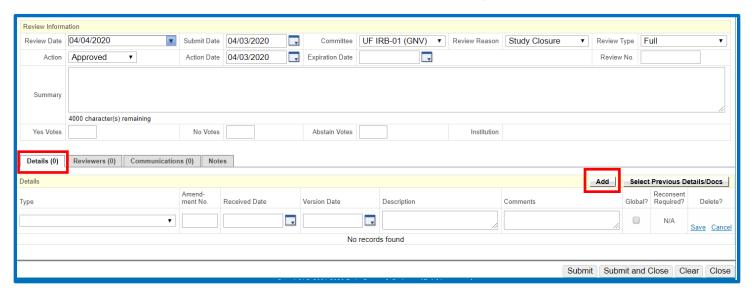
> ⚠️ **IMPORTANT:** *If the Review Date is not properly entered, OnCore will NOT retain the Review Date when the review record is submitted/closed. There are several areas of OnCore functionality that rely on properly entered review dates; For example, UF will not be able to invoice for close out fees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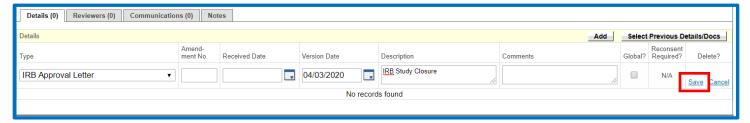
ADD IRB STUDY CLOSURE LETTER

1. If you are not currently in the applicable IRB record, <u>Find the IRB Review</u> where the closure was approved.

2. Click on the little blue **Edit** hyperlink next to the applicable review line.

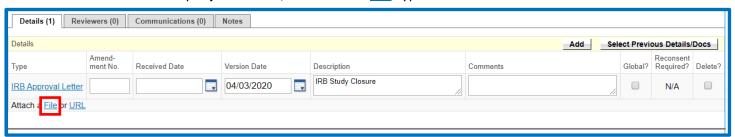3. In the **Details** section at the bottom of the IRB review record, click the **[Add]** button.

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.

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.
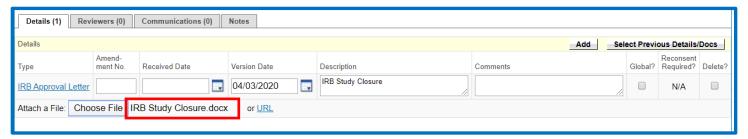

8. Click **[Browse]** or **[Choose File].**

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.

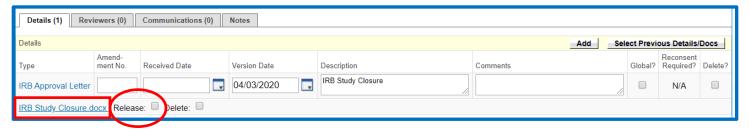11. Confirm that you now see the file name next to the **[Choose File]** button.

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

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

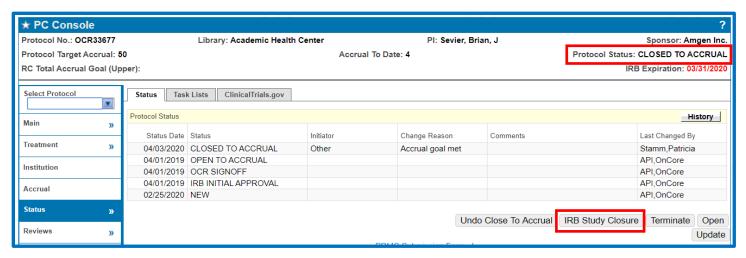14. Select the **[Release]** checkbox.

⚠️ *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.

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 and let them know it is time to close the study in UFIRST and myUFL.