DOCUMENT AN IRB REVIEW

Description: All IRB reviews and consents need to be recorded in OnCore. At UF, the approved consent forms should also be uploaded and attached to the applicable IRB review record; this makes them available for review when registering a subject to the study.

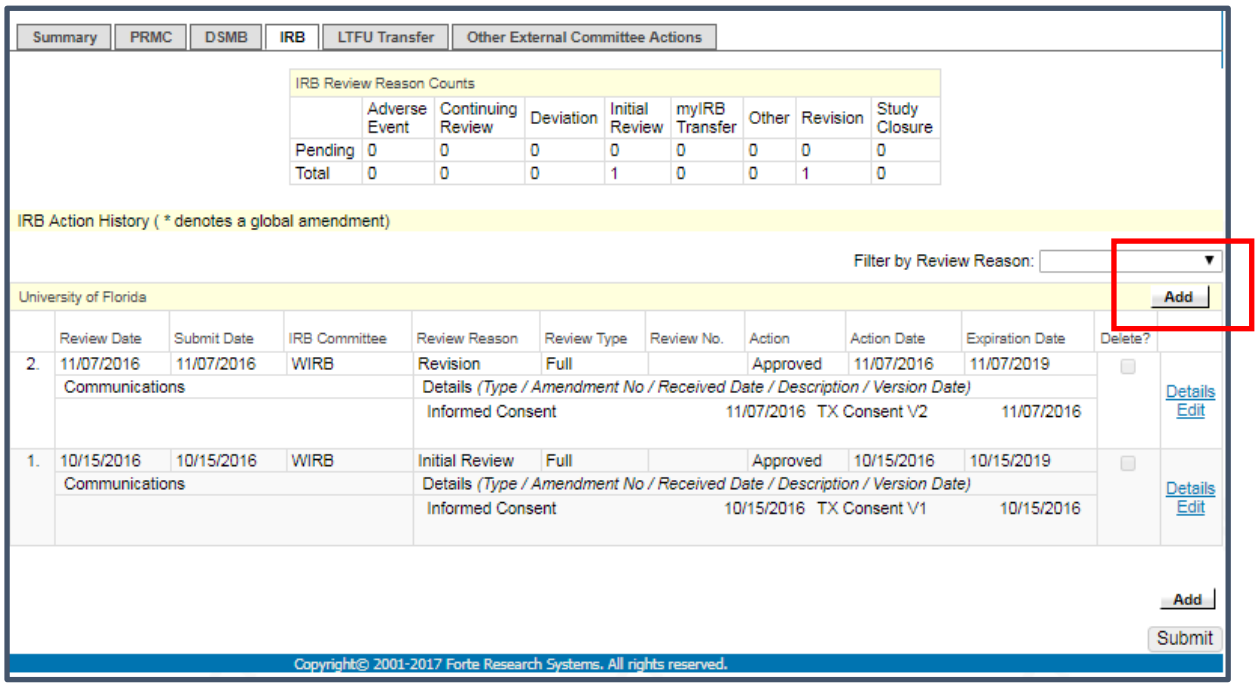
Other review documentation (e.g. IRB approval letters, Financial Language Assessments, approved advertising, subject surveys/questionnaires, etc.) can also be attached to the appropriate review record.

Once you have the initial IRB review and consents entered into OnCore, you can open the study to accrual. For details, see the Open a Protocol to Accrual user guide.

Audience: Any study staff member (e.g. **IRB Coordinator**) who is responsible for entering IRB information into OnCore.

RECORD THE IRB REVIEW

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, many sponsor invoiceable items are triggered by an IRB Review Date.*

6. Continue by entering the following required fields:
    - Submit Date
    - Committee
    - Review Reason
    - Review Type
    - Action
    - Action Date
    - Review Expires (Yes/No)

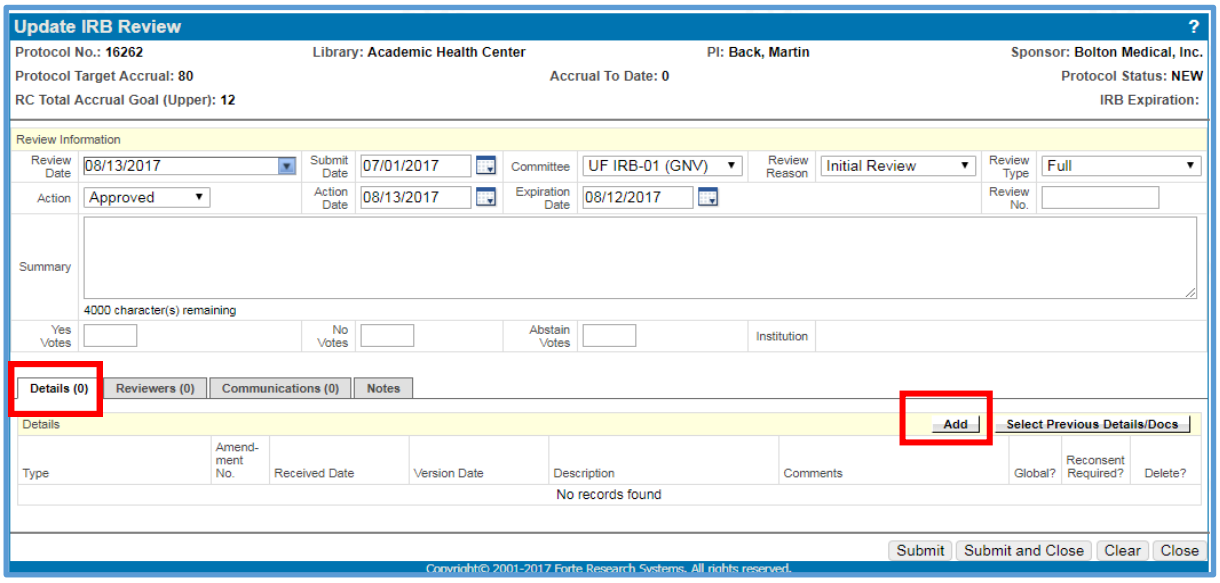
> ***IMPORTANT:*** *If the IRB Review Expires option is set to* ***No****, OnCore will not need any further reviews. The IRB Expiration date will show as N/A in the console header.*

    - 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.

> ***IMPORTANT:*** *If consents were approved and/or revised in this review, make sure that you upload them so they can be viewed when registering a subject (continue with instructions in next section).*

UPLOAD IRB APPROVAL LETTER AND CONSENT DOCUMENTS

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



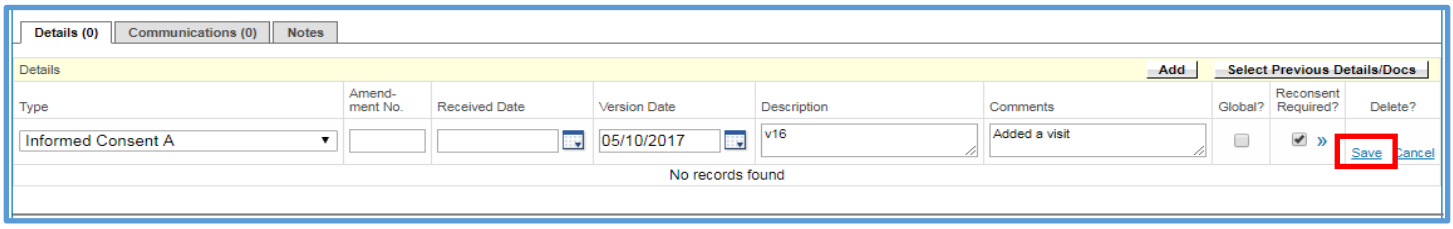
2. In the detail item row that appears, select the review item from the **Type** drop-down list (e.g. **IRB Approval Letter, Informed Consent** for a single consent, **Informed Consent A**, **Informed Consent B**, etc. for multiple consents).
3. Enter the **Version Date** of the consent.
4. Enter a **Description** for the consent (e.g. **Screening Consent**, **Treatment Consent**, etc.).

This description is very important for protocols with more than one consent. A good description will help the consenters find the correct consent (and the correct consent version) to use later in the **Subjects** console when they are consenting subjects to this study.

5. The **Comments** field is a good place to provide additional details about the consent.
6. If this is a revised consent and the IRB has required that all subjects be reconsented, select the **[Reconsent Required]** checkbox. This will place an "RR" flag on all enrolled subjects until they have signed the new consent and the reconsent has been recorded in OnCore. For details, see the Reconsent Subjects user guide.

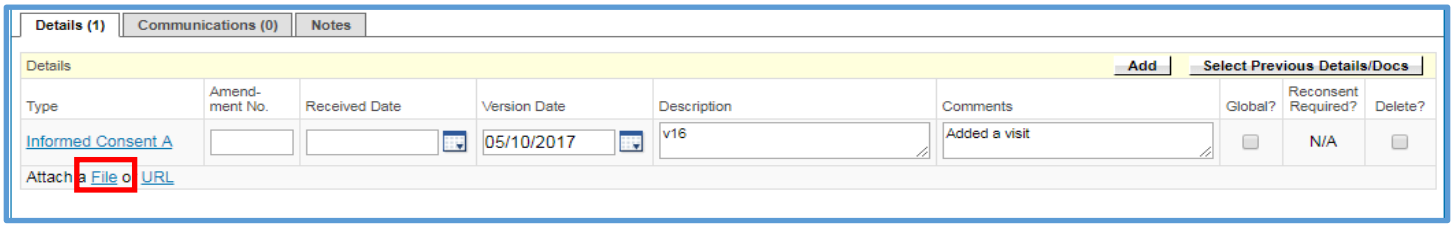
> ***IMPORTANT:*** *In order to activate the OnCore reconsenting functionality, the revised consent form you add must have the exact same document "**Type**" as the original version of the consent in the initial IRB review.*

7. Click the small blue **Save** on the far right.

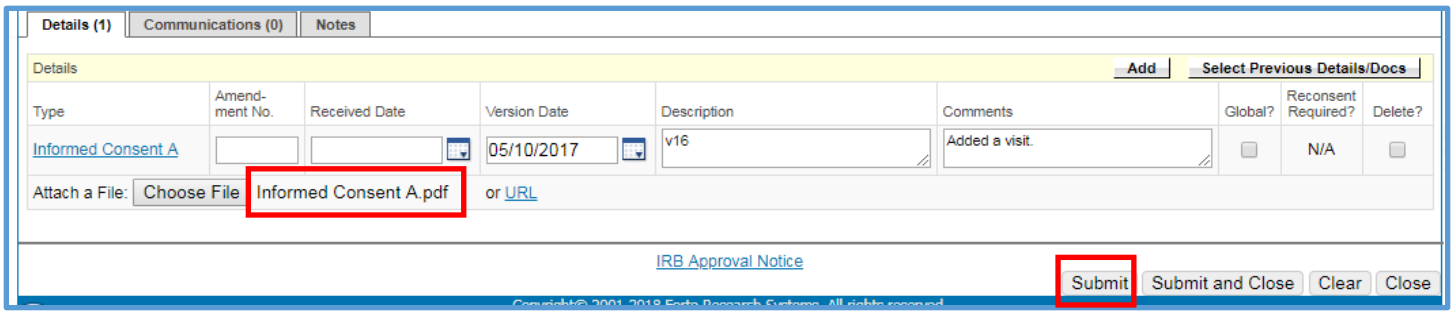


This creates a detail line that only describes the consent. **You will still need to attach the actual consent document** (*see next steps*).

8. Under the consent detail line you just created, click the blue **File** hyperlink.

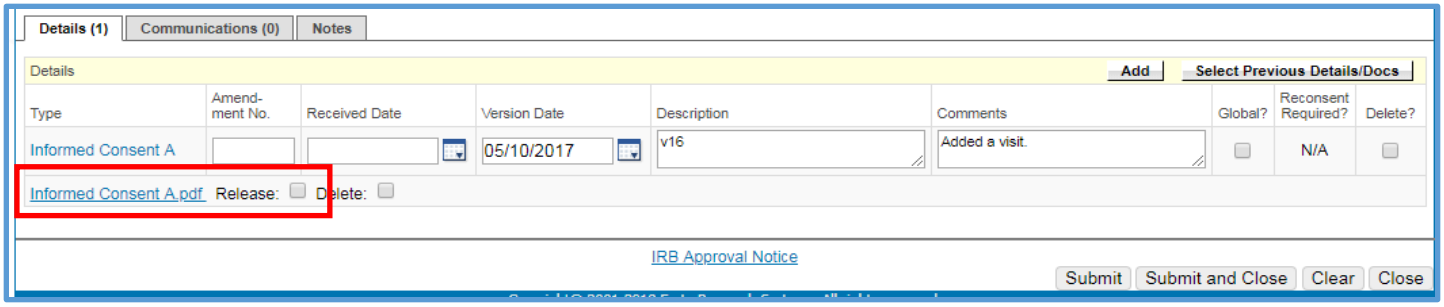


9. Click **[Browse]** or **[Choose File].**
10. Locate the consent form on your local computer or network hard drive and select it.
11. Click **[Open]** to upload the file to OnCore.
12. Confirm that you now see the consent document file name next to the **[Choose File]** button.



13. Click **[Submit]** to save this consent document to this record.

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



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

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

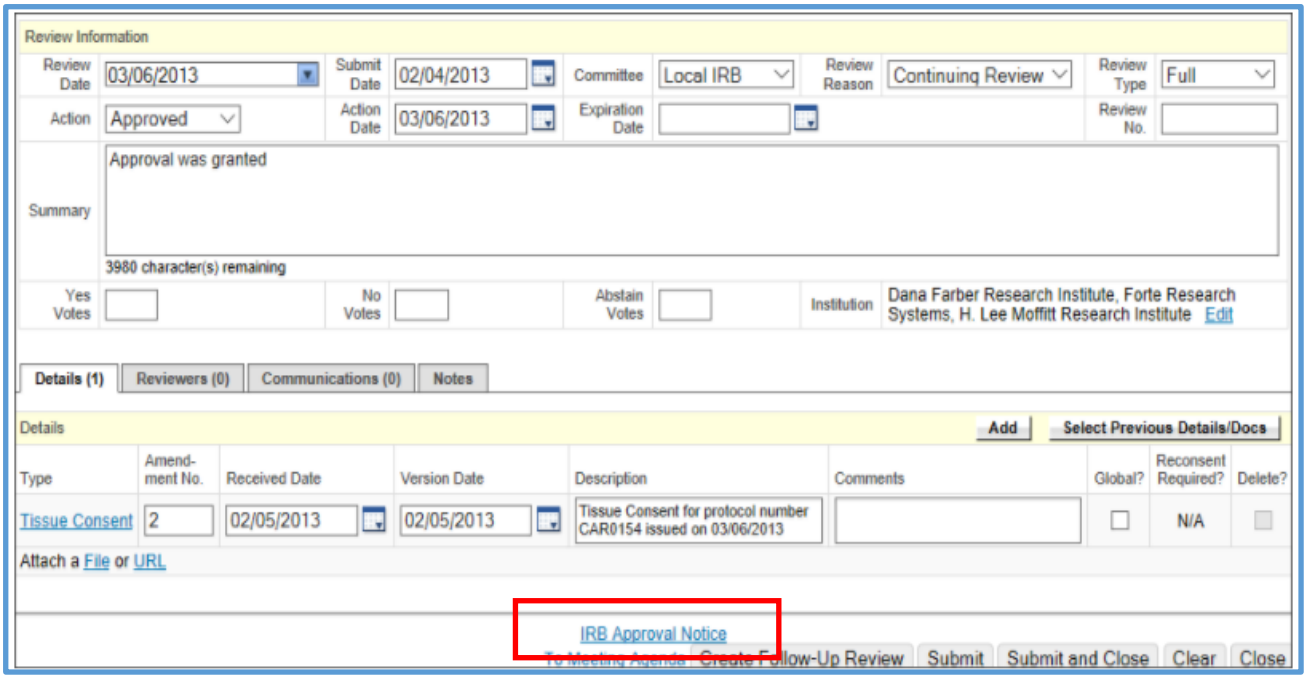
16. Click **[Submit]**.

17. Repeat steps 1 – 16 above to add each consent (or any other document applicable to this review).

    Note: Once you have the initial IRB review and consents entered into OnCore, you can open the study to accrual. For details, see the Open a Protocol to Accrual user guide.

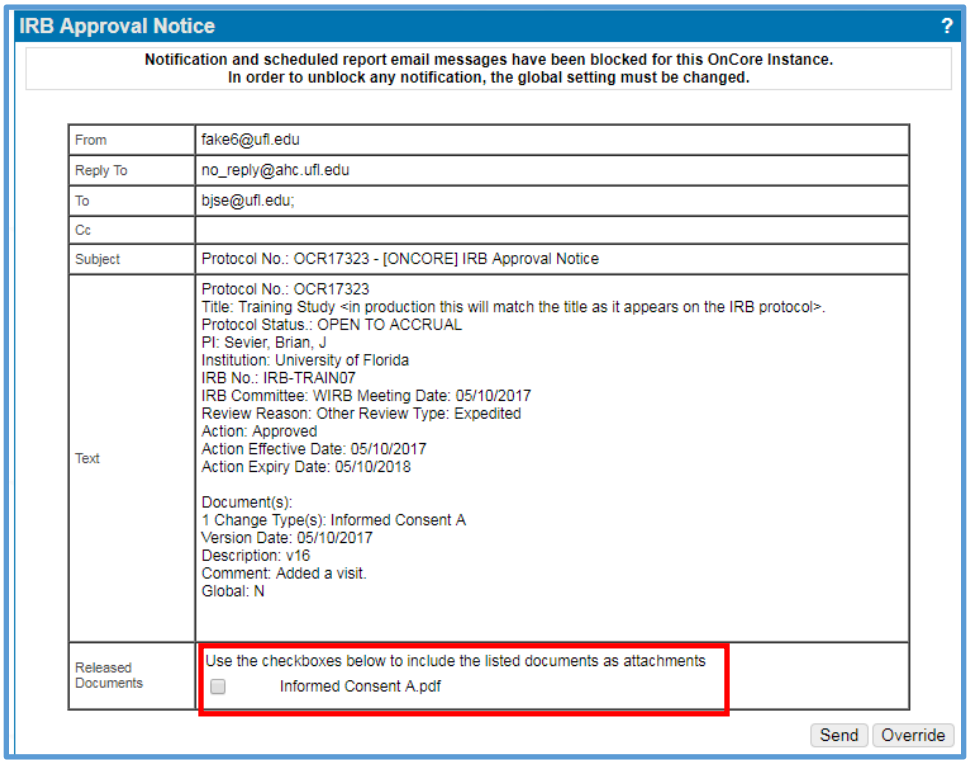
IRB APPROVAL NOTICE

Once an IRB review is saved with an **Action** of "**Approved**", a blue **IRB Approval Notice** hyperlink appears at the bottom of the **Details** section.



DOCUMENT AN IRB REVIEW

This is a manual notification; clicking the link displays an **IRB Approval Notice** page, where the notification can be edited before sending.



Files that have been uploaded to the review can be selected to send as attachments with the notification.

CLICK HERE TO VIEW DEMO VIDEO