

**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.

The screenshot shows the OnCore IRB Review interface. At the top, there are tabs for Summary, PRMC, DSMB, IRB, LTFU Transfer, and Other External Committee Actions. Below the tabs is a section for IRB Review Reason Counts, which includes a table with columns for Adverse Event, Continuing Review, Deviation, Initial Review, myIRB Transfer, Other, Revision, and Study Closure. The table shows 0 for all categories except Initial Review, which has a count of 1. Below this is the IRB Action History section, which includes a filter by Review Reason dropdown menu and an 'Add' button highlighted with a red box. The main table lists review records with columns for Review Date, Submit Date, IRB Committee, Review Reason, Review Type, Review No., Action, Action Date, Expiration Date, and Delete?. The table shows two records: one for a Revision (Full) on 11/07/2016 and one for an Initial Review (Full) on 10/15/2016. Both records are approved and have an expiration date of 11/07/2019. The table also includes a 'Details' link and an 'Edit' link for each record. At the bottom right, there are 'Add' and 'Submit' buttons. The footer of the page reads 'Copyright© 2001-2017 Forte Research Systems. All rights reserved.'

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.

**Update IRB Review**

Protocol No.: 16262      Library: Academic Health Center      PI: Back, Martin      Sponsor: Bolton Medical, Inc.  
Protocol Target Accrual: 80      Accrual To Date: 0      Protocol Status: **NEW**  
RC Total Accrual Goal (Upper): 12      IRB Expiration:

**Review Information**

Review Date: 08/13/2017    Submit Date: 07/01/2017    Committee: UF IRB-01 (GNV)    Review Reason: Initial Review    Review Type: Full

Action: Approved    Action Date: 08/13/2017    Expiration Date: 08/12/2017    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?
No records found								

Submit    Submit and Close    Clear    Close

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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.

- The **Comments** field is a good place to provide additional details about the consent.
- 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.

- Click the small blue [Save](#) on the far right.

Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
Informed Consent A			05/10/2017	v16	Added a visit	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

No records found

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

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

Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
<a href="#">Informed Consent A</a>			05/10/2017	v16	Added a visit	<input type="checkbox"/>	N/A	<input type="checkbox"/>

Attach a [File](#) or [URL](#)

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

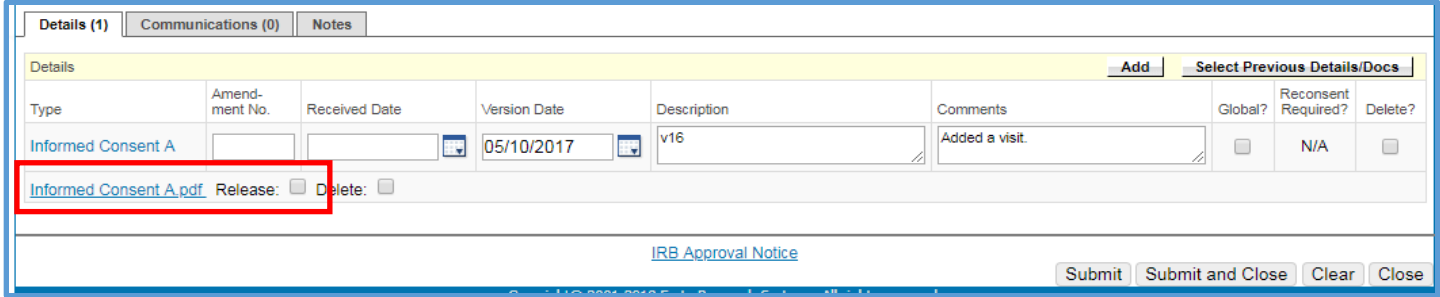
Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
<a href="#">Informed Consent A</a>			05/10/2017	v16	Added a visit.	<input type="checkbox"/>	N/A	<input type="checkbox"/>

Attach a File:  **Informed Consent A.pdf** or [URL](#)


[IRB Approval Notice](#)

- 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.*

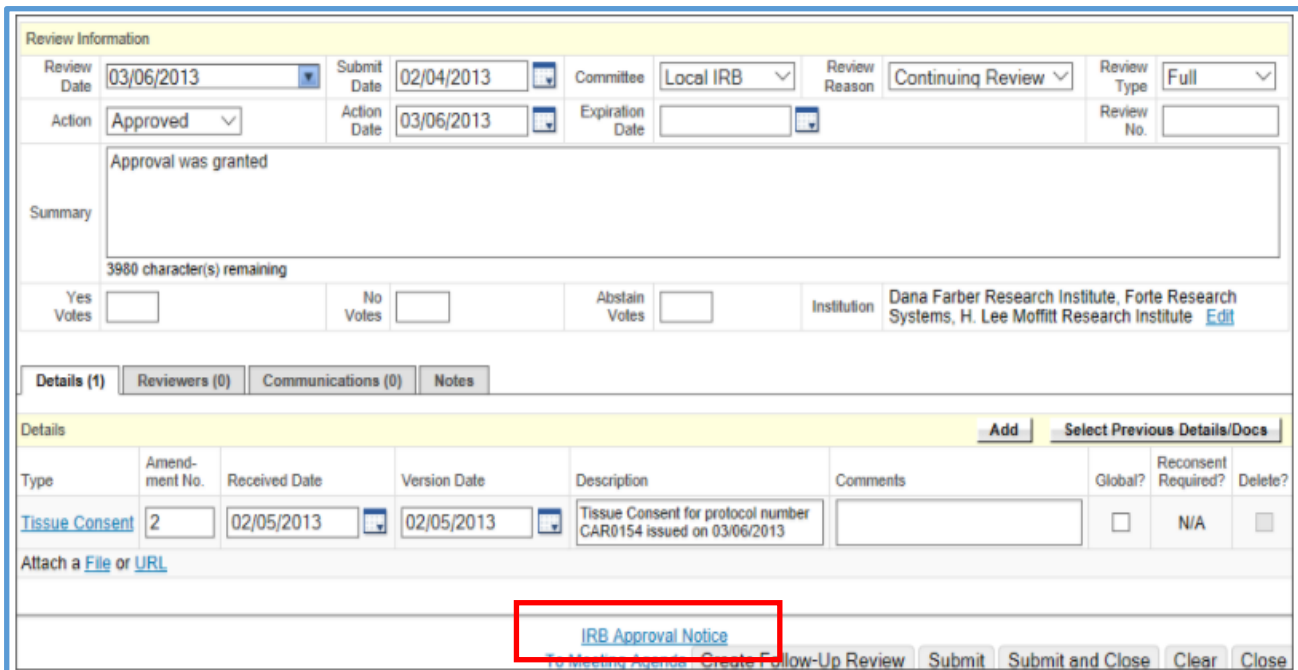
16. Click **[Submit]**.

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.



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

**IRB Approval Notice** ?

Notification and scheduled report email messages have been blocked for this OnCore Instance.  
In order to unblock any notification, the global setting must be changed.

From	fake6@ufl.edu
Reply To	no_reply@ahc.ufl.edu
To	bjse@ufl.edu;
Cc	
Subject	Protocol No.: OCR17323 - [ONCORE] IRB Approval Notice
Text	Protocol No.: OCR17323 Title: Training Study <in production this will match the title as it appears on the IRB protocol>. Protocol Status.: OPEN TO ACCRUAL PI: Sevier, Brian, J Institution: University of Florida IRB No.: IRB-TRAIN07 IRB Committee: WIRB Meeting Date: 05/10/2017 Review Reason: Other Review Type: Expedited Action: Approved Action Effective Date: 05/10/2017 Action Expiry Date: 05/10/2018  Document(s): 1 Change Type(s): Informed Consent A Version Date: 05/10/2017 Description: v16 Comment: Added a visit. Global: N
Released Documents	<p>Use the checkboxes below to include the listed documents as attachments</p> <p><input type="checkbox"/> Informed Consent A.pdf</p>

Send Override

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

[CLICK HERE TO VIEW DEMO VIDEO](#)