

UPLOAD IRB APPROVAL AND CONSENT DOCUMENTS

Description: When an IRB Review is documented, you must upload the applicable approval letter and consent documents into the correct IRB record.

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.

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

ADD IRB APPROVAL AND CONSENT DOCUMENTS

1. If you are not currently in the applicable IRB record, [Find the IRB Review](#) where the consents were 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.

The screenshot shows the 'Update IRB Review' interface. At the top, it displays protocol details: 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, and IRB Expiration. Below this is the 'Review Information' section with fields for 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), and Review No. There is a 'Summary' text area with a 4000 character limit. Below the summary are 'Yes Votes', 'No Votes', and 'Abstain Votes' fields. The 'Details' section is highlighted with a red box and contains a table with columns: Type, Amendment No., Received Date, Version Date, Description, Comments, Global?, Reconsent Required?, and Delete?. The table currently shows 'No records found'. An 'Add' button is highlighted with a red box next to the 'Details' section. At the bottom of the form are 'Submit', 'Submit and Close', 'Clear', and 'Close' buttons.

4. 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).
5. Enter the **Version Date** of the consent.
6. 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.
7. The **Comments** field is a good place to provide additional details about the consent.
8. 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.

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

The screenshot shows the 'Details' tab of the OnCore system. A table with columns for Type, Amendment No., Received Date, Version Date, Description, Comments, Global?, Reconsent Required?, and Delete? is visible. A new row is being added with 'Informed Consent A' as the type, 'v16' as the description, and 'Added a visit' as the comment. The 'Save' button at the bottom right of the row is highlighted with a red box.

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

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

The screenshot shows the 'Details' tab with one record. The 'File' hyperlink under the 'Attach a File or URL' field is highlighted with a red box.

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

12. Locate the consent form on your local computer or network hard drive and select it.

13. Click **[Open]** to upload the file to OnCore.

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

The screenshot shows the 'Details' tab with the file 'Informed Consent A.pdf' now attached to the record. The 'Submit' button at the bottom right is highlighted with a red box.

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

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

The screenshot shows the 'Details' tab with the file 'Informed Consent A.pdf' attached. The 'Release' checkbox is now visible next to the file name, and the 'Submit' button at the bottom right is highlighted with a red box.

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

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

18. Click [**Submit**].
19. 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.

[CLICK HERE TO VIEW DEMO VIDEO](#)