## UPLOAD IRB APPROVAL AND CONSENT DOCUMENTS

**UF OnCore Tip Sheet**Version 05/18/23

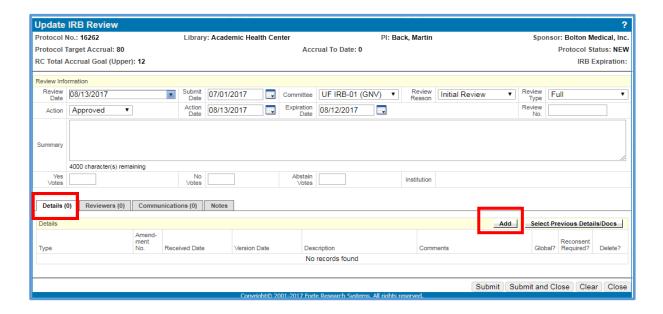
**Description:** When an IRB Review is documented, you must upload the applicable approval letter and consent documents into the correct IRB record.

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.



- 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.

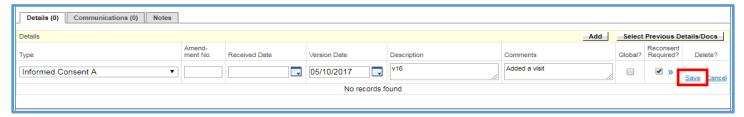


**IMPORTANT:** In order to activate the OnCore reconsenting functionality, the revised consent form you add must have the exact same document "**Type**" as the original version of the consent in the initial IRB review.

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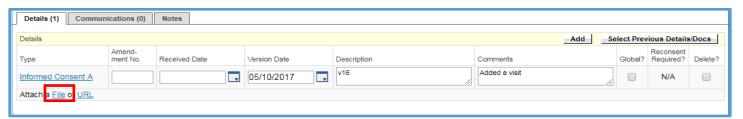
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9. Click the small blue Save on the far right.

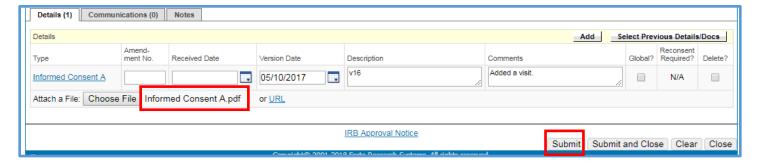


This creates a detail line that only describes the consent. You will still need to attach the actual consent document (see next steps).

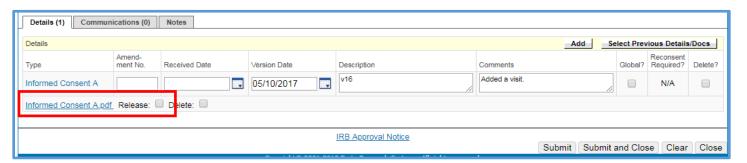
10. Under the consent detail line you just created, click the blue File hyperlink.



- 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.



- 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.



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 <u>Open a Protocol to Accrual</u> user guide.

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