Documenting an Initial IRB Approval & Opening a Protocol to Accrual

All protocols in OnCore must have an IRB review documented before opening to accrual. In this guide, we will show the minimum necessary IRB documentation required to open a study to accrual in OnCore. OnCore can send a notification to appropriate staff members when an IRB review is about to expire.

1. Document the IRB of Record Approval

The following instructions show you how to record the IRB approval information on the **PC Console > Reviews > IRB** tab.

1. *Navigate to PC Console > Reviews.

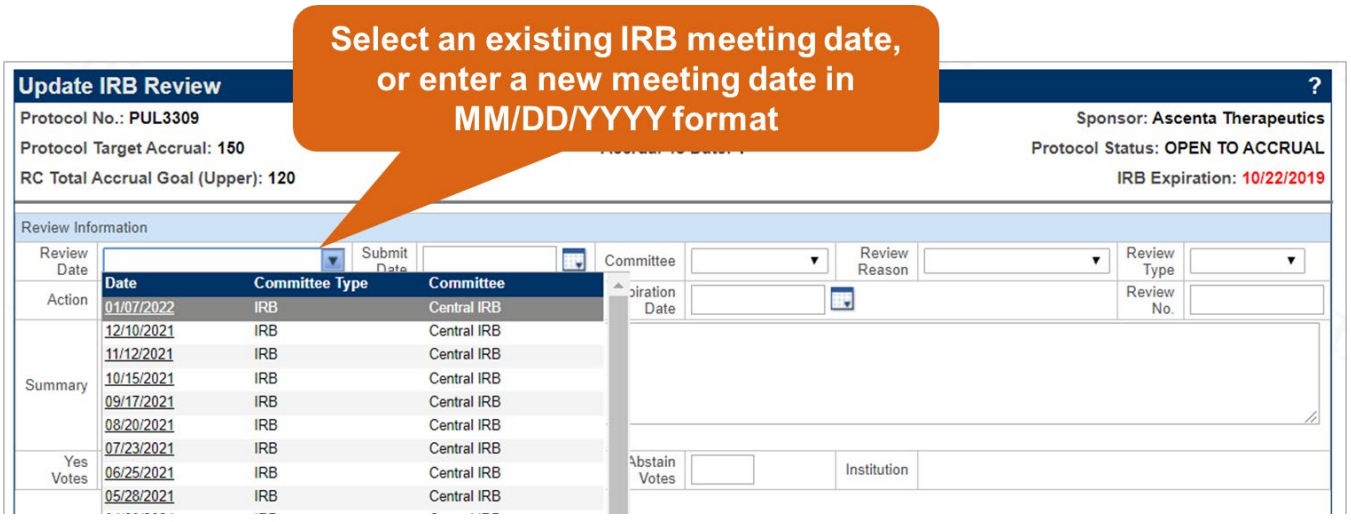
   NOTE: The Summary tab provides a read-only view of all IRB committee reviews that have been documented for this protocol, as well as other types of institutional reviews. For a new protocol, this tab is blank because no reviews have occurred.

2. *To document an IRB initial review for this protocol, click the **IRB** tab on the horizontal menu.

3. *Click **Add**.

4. *In the **Review Date** field, select the date the IRB convened, or if unavailable, the date of approval. For example, enter: **07/23/2021**.

   NOTE: The Review Date field is unique in that it does not have "date widget" functionality. If a Review Date is not available, you can enter a date using MM/DD/YYYY format.



5. *Indicate that the review was submitted on a date that is prior to or equal to the date of committee review. For example, enter:

    - **Submit Date**: 06/15/2021

6. *Choose the committee that reviewed this protocol. For example:

    - **Committee:** WIRB

7. *Enter the type and reason for the review:

    - **Review Reason**: Initial Review
    - **Review Type**: Full

8. *Indicate the committee's action and the review's expiration:

    - **Action**: Approved
    - **Action Date**: 07/23/2021
    - **Review Expires**: Yes
    - **Expiration Date**: 07/23/2022
    - **Review No**.: 20227845 *(Corresponds to the IRB review tracking number)*

    NOTE: The IRB Expiration date is shown in the PC Console header after adding the IRB Initial Review. The date is shown in red if it is past the IRB Expiration date.

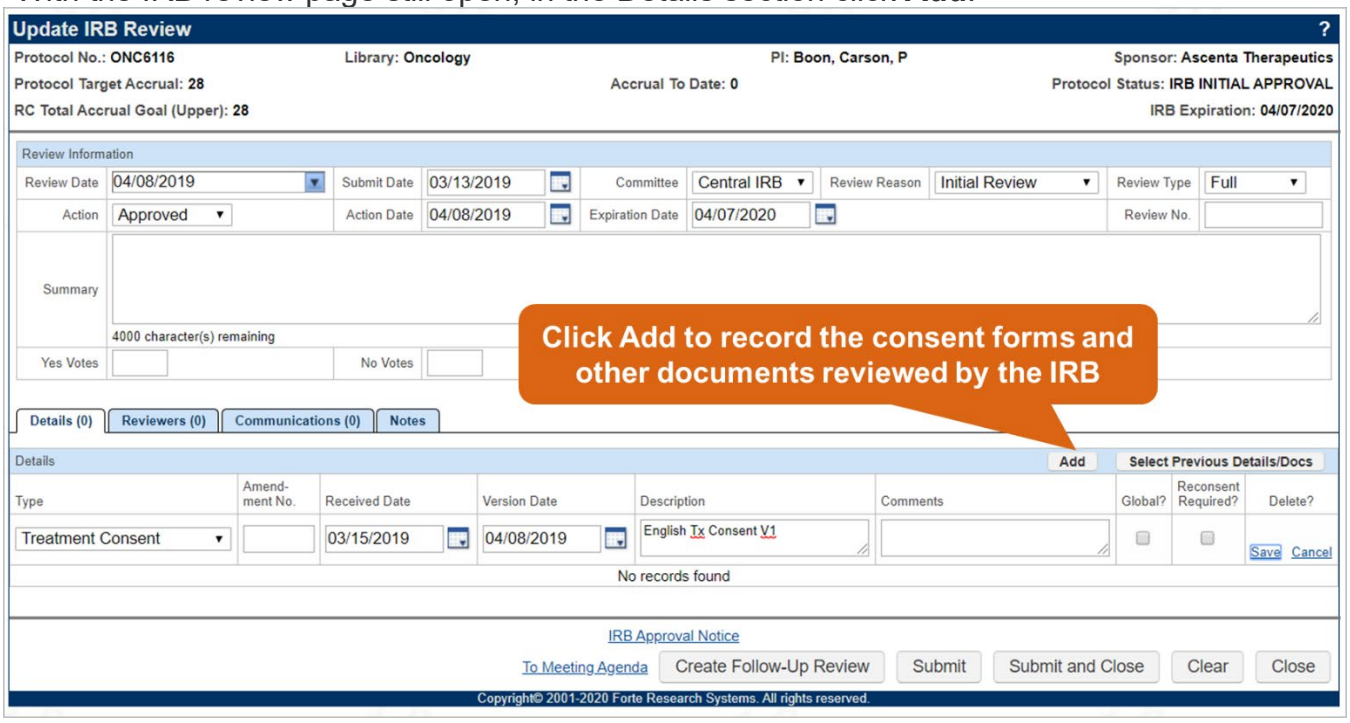
9. Optional: The review summary and voting record fields are not required and may be left blank.

10. Continue to Section 2 to complete the IRB documentation.

2. *Add and attach IRB approved documents and IRB letters

In the Details tab beneath the Review Information, all documents that were approved by the IRB, as well as the accompanying IRB review documentation should be uploaded. **At a minimum, the approved informed consent forms(s) and the IRB approval letter are required** to be uploaded as attachments to the Initial Review.

11. *With the IRB review page still open, in the Details section click **Add**.



12. *Choose **C-Treatment Consent** in the Type field to upload the main study informed consent form.

13. *In the **Received Date** field, indicate the date that the IRB released the approved document. In the **Version Date**, indicate the version date of the document, typically found in the header or footer.

14. *Type a brief description for this consent form, to help study team members distinguish between different versions in the future. For example:

    - **Description:** English Tx Consent V1

    NOTE: For each uploaded document, the only fields that are required are: **Type**, **Received Date**, **Version Date**, while the **Amendment No.**, **Description**, and **Comments** are encouraged, but not required.

Good to know!

ICF(s) uploaded here will automatically populate in the Subject Console as options to document each subject's consent. Therefore, before a protocol status may be moved to **Open to Accrual**, the approved ICF(s) MUST be attached to a Review Reason of **Initial Review**, or in some cases, **Consent Form**.

15. *Click **Save** to reveal the document upload hyperlink with which you will attach the corresponding ICF document.

16. *To attach the consent document, click **File**, and then click **Choose File**. Select the document from your computer files and then click **Submit.**

17. *Select the **Release** checkbox and then click **Submit**.

18. *Repeat steps 10-15 for additional ICF(s) and the IRB approval letter. Any other documents associated with the review are also encouraged to be uploaded.

    NOTE: Releasing an attached document makes it available (to users with the appropriate permissions) in Protocols > Document Search. Non-consent forms that are attached to IRB reviews and released will also be available on the PC Console > Documents tab.

19. *Click **Submit**.

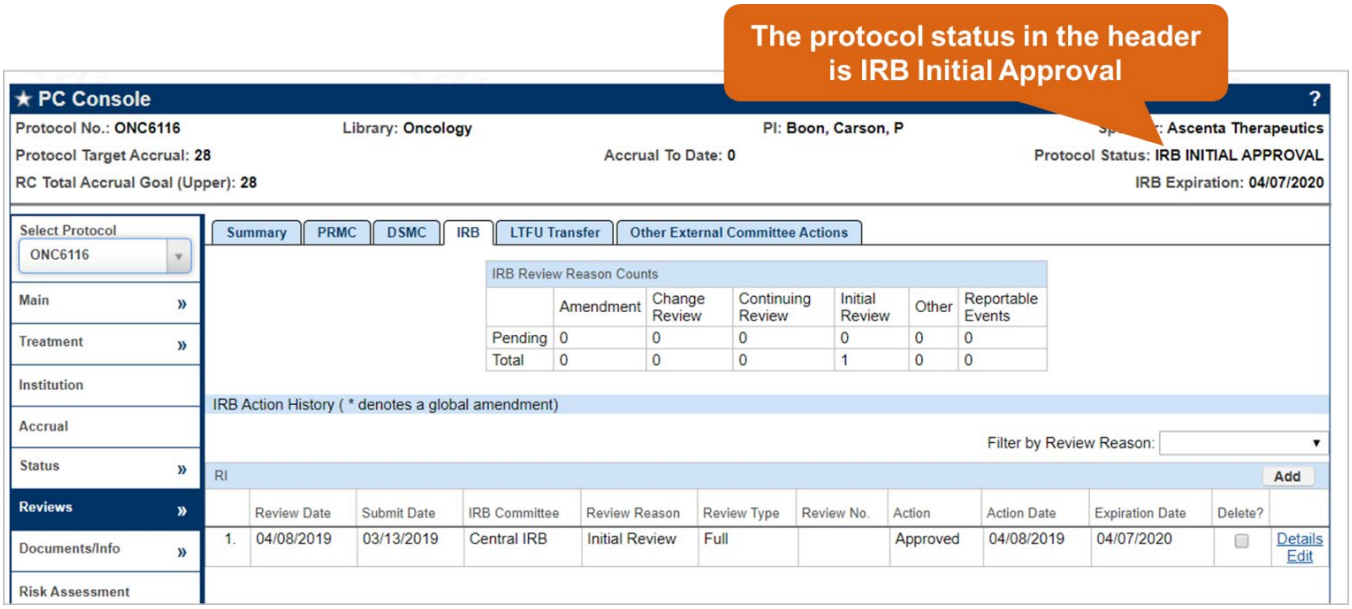
20. Optional: If you would like to effortlessly inform your study team of the approval and distribute the uploaded documents, click the **IRB Approval Notice** hyperlink beneath the uploaded document log lines. A preview of the email notification and the default recipients is shown.

21. Check the boxes of each document you would like to distribute with the email notice.

22. To edit the default notice or add additional recipients, click **Override**.

23. Click **Send**.

24. The Protocol Status will now show as “IRB INITIAL APPROVAL” in the header.

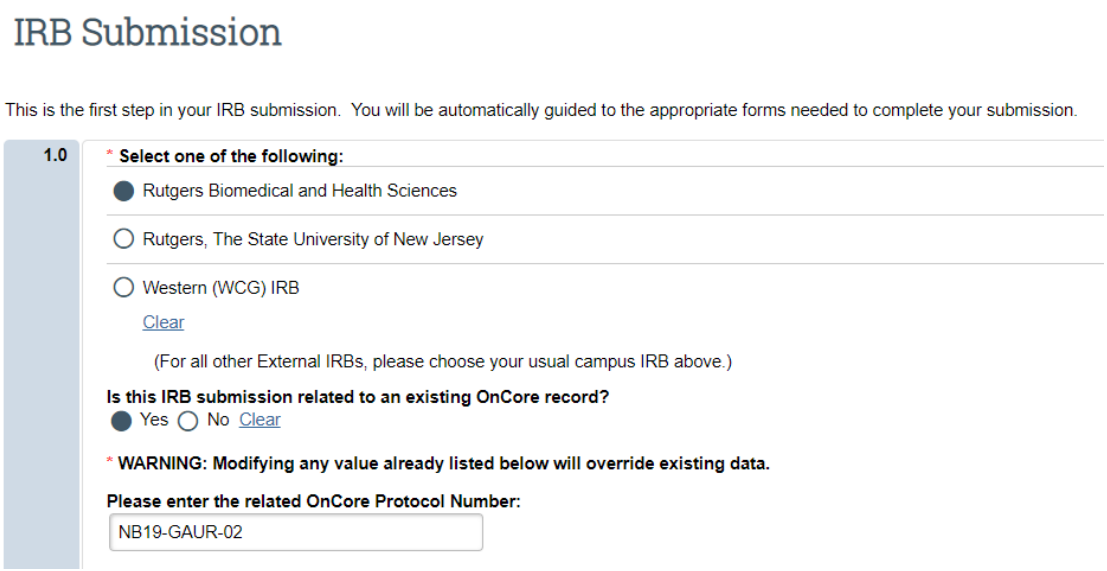


3. Documentation of a local Rutgers' IRB review in OnCore

There is an integration built connecting OnCore with eIRB that allows certain information to flow between eIRB and OnCore. The following instructions show you how the integration pushes Rutgers' IRB approvals and acknowledgments over to OnCore within the **IRB Reviews** tab.

> **NOTE:** In order to ensure the integration works properly, studies must be submitted to OnCore and assigned an OnCore **Protocol No.** (e.g., NB19-GAUR-02) prior to creating an eIRB application. When in eIRB, you will be prompted to enter the OnCore **Protocol No.**, which will trigger the integration between eIRB and OnCore.

1. *When completing an eIRB application, indicate that the submission relates to an OnCore submission and enter the OnCore number. This will pull all of the relevant OnCore data and pre-fill certain eIRB fields.



2. After your submission to eIRB is pending, the review will automatically document in OnCore.

3. Navigate to PC Console > Reviews.

4. Click the **IRB** tab on the horizontal menu.

5. Locate **Rutgers eIRB** under the IRB Committee column. Click **Details** for a view-only option or **Edit** to make adjustments.

4. Opening a Protocol for Accrual

After the initial IRB approval and ICF(s) are uploaded to OnCore and the RBHS Clinical Trials Office generates the **CTO Signoff** protocol status (indicating that all study startup-related activities are complete), the study team will receive an email notification indicating that the study can be opened for subject recruitment and accrual. The following steps will show you how to change the protocol status to **Open to Accrual**.

1. After **CTO Signoff** status is complete, the **Open** button will appear in PC Console.
2. *In the PC Console > Status tab, click **Open**.
3. *Your example protocol received all appropriate signoffs in July 2021 and opened for accrual in August. Enter a **Status Date** of **8/5/2021** and then click **Submit**.
4. The protocol now has a status of Open to Accrual in the PC Console header and the study is now eligible to register subjects in the CRA Console.