

## 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.

Select an existing IRB meeting date,  
or enter a new meeting date in  
**MM/DD/YYYY format**

Review Information			Committee	Review Reason	Review Type
Review Date	Action	Date	Committee	Type	Committee
Summary	01/07/2022	IRB	Central IRB		
	12/10/2021	IRB	Central IRB		
	11/12/2021	IRB	Central IRB		
	10/15/2021	IRB	Central IRB		
	09/17/2021	IRB	Central IRB		
	08/20/2021	IRB	Central IRB		
	07/23/2021	IRB	Central IRB		
Yes Votes	06/25/2021	IRB	Central IRB		
	05/28/2021	IRB	Central IRB		
Abstain Votes			Institution		

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.

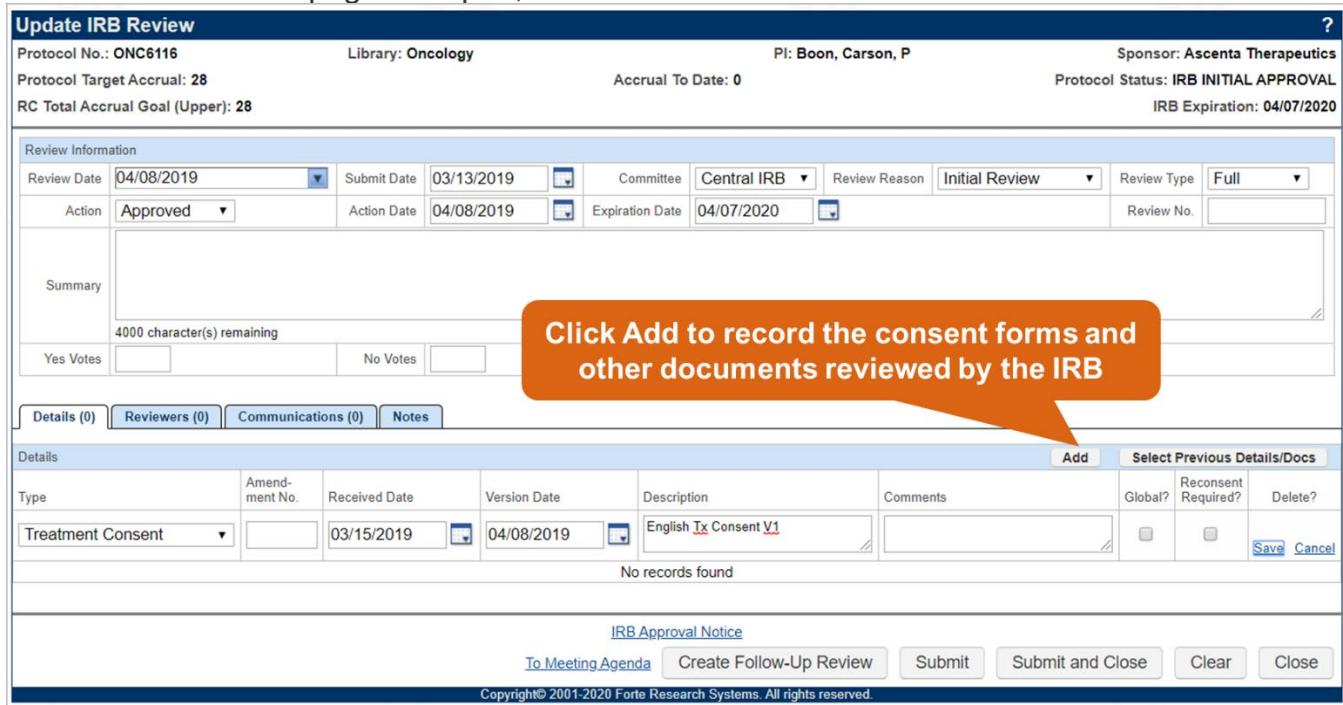
9. Optional: The review summary and voting record fields are not required and may be left blank.

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**.



The screenshot shows the 'Update IRB Review' interface. At the top, it displays protocol information: Protocol No.: ONC6116, Library: Oncology, PI: Boon, Carson, P, Sponsor: Ascenta Therapeutics. Below this is the 'Review Information' section with fields for Review Date (04/08/2019), Submit Date (03/13/2019), Committee (Central IRB), and Review Reason (Initial Review). An orange callout bubble with the text 'Click Add to record the consent forms and other documents reviewed by the IRB' points to the 'Add' button in the 'Details' table header. The 'Details' table lists a single document entry: Type (Treatment Consent), Received Date (03/15/2019), Version Date (04/08/2019), Description (English Tx Consent V1), and Comments (empty). Buttons at the bottom include 'Add', 'Select Previous Details/Docs', 'Save', and 'Cancel'.

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

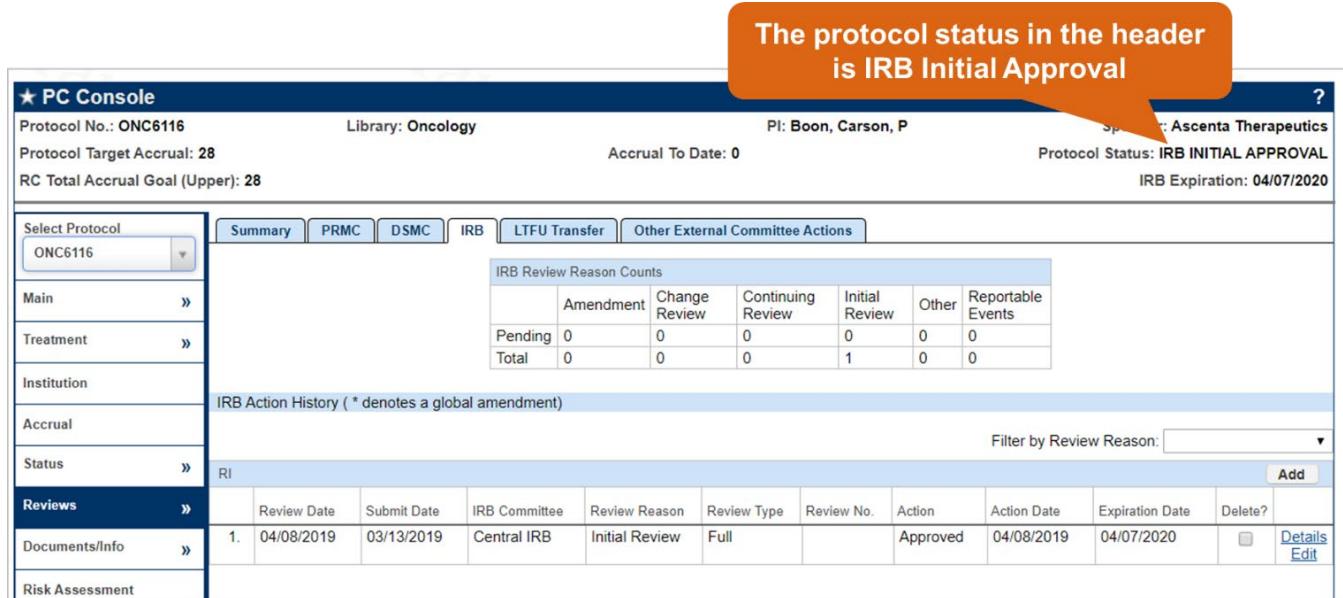
**NOTE:** For each uploaded document, the only fields that are required are: **Type**, **Received Date**, **Version Date**, while the **Amendment No.**, **Description**, and **Comments** are encouraged, but not required.

### 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.

The protocol status in the header is IRB Initial Approval



The screenshot shows the PC Console interface for protocol ONC6116. The header displays "Protocol Status: IRB INITIAL APPROVAL". The main content area shows IRB Review Reason Counts and an IRB Action History table. The IRB Action History table has the following data:

	Pending	Amendment	Change Review	Continuing Review	Initial Review	Other	Reportable Events
Total	0	0	0	1	0	0	

At the bottom of the screenshot, there is a table for "Review Date", "Submit Date", "IRB Committee", "Review Reason", "Review Type", "Review No.", "Action", "Action Date", "Expiration Date", and "Delete?". The first row contains the following values:

Review Date	Submit Date	IRB Committee	Review Reason	Review Type	Review No.	Action	Action Date	Expiration Date	Delete?
04/08/2019	03/13/2019	Central IRB	Initial Review	Full		Approved	04/08/2019	04/07/2020	<input type="checkbox"/> Details Edit

### 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.

#### IRB Submission

This is the first step in your IRB submission. You will be automatically guided to the appropriate forms needed to complete your submission.

1.0     \* **Select one of the following:**

Rutgers Biomedical and Health Sciences

Rutgers, The State University of New Jersey

Western (WCG) IRB

[Clear](#)

(For all other External IRBs, please choose your usual campus IRB above.)

**Is this IRB submission related to an existing OnCore record?**

Yes  No [Clear](#)

\* **WARNING: Modifying any value already listed below will override existing data.**

**Please enter the related OnCore Protocol Number:**

NB19-GAUR-02

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.