

DOCUMENT AN IRB REVIEW

Description: All IRB reviews and consents need to be recorded in OnCore. 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 can also be attached to the appropriate review record.

Entering the initial IRB review, IRB approval letter, and consent(s) into OnCore is **required** before you can open the study to accrual.

Audience: Any study staff member who is responsible for entering IRB information into OnCore (i.e. coordinators).

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**. Click the **IRB** horizontal tab.
4. Click the **[Add]** button.

The screenshot shows the OnCore PC Console interface. On the left is a vertical menu with options: Select Protocol (IRBDEMO), Main, Treatment, Institution, Accrual, Status, and Reviews. The top navigation bar has tabs: Summary, PRMC, DSMC, IRB (highlighted), LTFU Transfer, and Other External Committee Actions. The main content area displays an 'IRB Review Reason Counts' table and an 'IRB Action History' section with 'No Records Found'. An 'Add' button is highlighted in the bottom right corner.

IRB Review Reason Counts						
	Amendment	Change Review	Continuing Review	Initial Review	Other	Reportable Events
Pending	0	0	0	0	0	0
Total	0	0	0	0	0	0

IRB Action History (* denotes a global amendment)

No Records Found

Add

Submit

5. In the **Review Date** field, type in the date of the IRB Review, using the date format **MM/DD/YYYY**, and then make sure the date is entered by either clicking on the date hyperlink in the resulting dropdown list OR hitting the "Tab" key on your keyboard.

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Update IRB Review

Protocol No.: IRBDEMO Library: Medicine PI: David, Diemert Sponsor: Eli Lilly and Company
Protocol Target Accrual: 100 Accrual To Date: 0 Protocol Status: NEW
RC Total Accrual Goal (Upper): 30 IRB Expiration:

Review Information

Review Date	Type here to search	Submit Date	Committee	Review Reason	Review Type
Action		Action Date	Review Expires	Expiration Date	Review No.

Summary

4000 character(s) remaining

Yes Votes: No Votes: Abstain Votes: Institution:

Details (0) Reviewers (0) Communications (0) Notes

Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
No records found								

Submit Submit and Close Clear Close

6. Continue by entering the following **required** fields:

- Submit Date
- Committee
 - i. If your review was done by an outside IRB that isn't specifically listed in the Committee dropdown, select the "Outside IRB" option from the dropdown and record which IRB was used in the **Summary** text box.
- Review Reason
 - i. Amendment vs. Change Review: if the change involves a formal amendment to the protocol, select Amendment. Select Change Review for other changes that do not involve a protocol amendment (i.e., staff changes).
- Review Type
- Action
- Action Date
- Expiration Date

A note about the **Review Expires** field: This field will default to Yes, because the assumption is that your IRB review has an expiration date. If your review does not, in fact, expire, you can set this field to No. This will disable the Expiration Date field. The IRB Expiration text in the protocol header will read N/A.

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. The **Review Date**, **Review Reason**, and **Review Type** fields are especially important for financial reasons and should be double-checked.



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).

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ADD CONSENT DETAILS AND CONSENT DOCUMENTS

1. In the **Details** section at the bottom of the IRB review record, click the **[Add]** button.



IMPORTANT: You must attach your consent(s) to a **specific IRB review**. Attaching a consent separately by filling out the Details section in a new blank record (rather than filling out the Details section within the initial IRB review, continuing review, etc.) will **not** allow you to consent subjects to the study. This in turn will prevent the subjects from being associated with the study in Epic.

Details (0)				Reviewers (0)		Communications (0)		Notes			
Details								Add	Select Previous Details/Docs		
Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?			
No records found											

2. In the detail item row that appears, select the review item from the **Type** drop-down list (e.g. **Treatment Consent**). **Note:** Multiple consent types can be added to the Details table. **Treatment Consent** is the main ICF. HIPAA Consent is not—this option is present for times when the HIPAA authorization is a separate document from the ICF and therefore needs to be entered separately. Screening Consent is also not the ICF—it is for when screening activities require a separate consent form.

If you have more than one main ICF for a study (a pediatric ICF and one for adult patients, for example, or a Spanish-language ICF and an English-language one), each can be added as a separate Treatment Consent. Just be sure to use the Description field to record which consent each is, so that you can easily tell them apart when consenting a subject.

3. Enter the **Version Date** of the consent.
4. Enter a **Description** for the consent (optional—unless multiple Treatment Consents are being added, in which case you will want to use this field to label each consent for easy differentiation).
 - a. You can use either the **Description** field or the **Comments** field to note the version of a document.
 - b. If you want to note the number of an amendment to a document, you can mark this in the **Amendment No.** field. For an initial document (with no amendments yet), this field should either be blank or have a “0” in it. The first amendment would then be “1”. In general, the amendment number should correspond to the version of the protocol that the document refers to.
5. The **Comments** field is a good place to provide additional details about the consent.
6. For revised consents only (for instance, a consent attached to a continuing review): if 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.

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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?
Treatment Consent		05/01/2021	04/01/2021	V1		<input type="checkbox"/>	<input type="checkbox"/>	Save Cancel

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?
Treatment Consent		05/01/2021	04/01/2021	V1		<input type="checkbox"/>	N/A	<input type="checkbox"/>
Attach: File or URL								

- Click **[Browse]** or **[Choose File]**.
- Locate the consent form on your local computer or Box drive and select it. (All uploaded consents should be in PDF format.)
- 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?
Treatment Consent		05/01/2021	04/01/2021	V1		<input type="checkbox"/>	N/A	<input type="checkbox"/>
Attach a File: Choose File Testing_ICF.pdf or URL								


[To Meeting Agenda](#) [Create Follow-Up Review](#) [Submit](#) [Submit and Close](#) [Clear](#) [Close](#)

- Click **[Submit]** to save this consent document to this record.
- Confirm that you now see a **blue hyperlink** for the consent to the left of a **Release** checkbox.

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Details (1)		Reviewers (0)		Communications (0)		Notes				
Details								Add	Select Previous Details/Docs	
Type	Amend-ment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?		
Treatment Consent		05/01/2021	04/01/2021	V1		<input type="checkbox"/>	N/A	<input type="checkbox"/>		
Testing_ICF.pdf		Release: <input checked="" type="checkbox"/>	Delete: <input type="checkbox"/>							

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



*If you miss selecting the **Release** checkbox, the new consent will not be searchable or downloadable for other users who might need it, so always remember to check that box.*

16. Click **[Submit]** or **[Submit and Close]**.

17. Repeat steps 1 – 16 above to add each consent (or any other document applicable to this review).

ADD THE IRB APPROVAL LETTER

1. Follow steps 1-16 in the **Add Consent Details and Consent Documents** section above, selecting “IRB approval letter” in the Type field. The IRB approval letter is now required to be added and uploaded when you document an IRB review. This is especially important for any study that involves the IDS Pharmacy staff, as they need to be able to access these letters.
2. Remember to check the **[Release]** checkbox for your IRB approval letter. Documents that are not consents will show up on the Documents/Info tab so long as you remember to check the Release checkbox.

Note: Once you have the initial IRB review, consent(s), and approval letter entered into OnCore, the study status will change to IRB INITIAL APPROVAL. Upon reaching this status, the study can be opened to accrual within the system.

★ PC Console				?
Protocol No.: IRBDEMO	Library: Medicine	PI: David, Diemert	Sponsor: Eli Lilly and Company	
Protocol Target Accrual: 100		Accrual To Date: 0	Protocol Status: IRB INITIAL APPROVAL	
RC Total Accrual Goal (Upper): 30			IRB Expiration: 05/01/2022	