

MCW uses eBridge to electronically track Human Research submissions. Currently, there is no electronic interface between eBridge and OnCore. To minimize the redundancy between the two systems, the following is a list of the minimum required IRB reviews to be documented in OnCore to assure the most current consent(s) and protocol will always be available in the system. Depending on the functionality you are using, such as auditing or SAE tracking, you may wish to document additional IRB reviews.

### Types of IRB Reviews to Record

Review Type	Rationale
<b>REQUIRED IRB REVIEWS</b>	
Initial Review	Necessary to open a study to accrual
All CPRs	Extends the IRB Expiration Date in OnCore & the most current consent form(s) can be uploaded
Amendments	Adding Protocol Amendments which modify the Protocol and/or Consent(s) is required. This assures the most current protocol/consent can be uploaded in the Details tab and be available in OnCore.
<b>OPTIONAL IRB REVIEWS</b>	
Non-protocol Amendments	
Reportable Events	



## Recording an IRB Review in the Review Information section

**Update IRB Review** ?

Protocol No: **SCREENSHOTS**    Library: **MCW General**    PI:    Sponsor:

Protocol    **Enter the "Received by IRB Office" date from eBridge. Do NOT enter the "Submitted Application" date.**    **al To Date: 0**    **Protocol Status: NEW**

RC Total    **IRB Expiration:**

Review Information

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

**Review Date:** Select the IRB Committee Meeting Date. The date widgets do not work in this field. Either type the date in the format xx/xx/xxxx or enter the month/date to filter the list

The Action & Expiration Dates are the dates listed in the IRB Approval Letter

Enter the entire number:  
 PRO00010000  
 AME00010000  
 RE00100000  
 CPR00010000

May be copied and pasted directly from eBridge.

**Note: The Review Date and Action Date on the IRB's decision letter will usually be the same unless the submission was tabled**

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



## IRB Documents

The Details Tab is where IRB-related documents are uploaded by clicking “Add”.

### IRB Documents to Upload

REQUIRED DOCUMENTS	
Consent 1	Consent 1 is the Study’s Main Consent. All approved consents must be uploaded.
Consent 2-5 if applicable	For additional Consents (e.g. Blood, Banking, Screening etc.)
Protocol	
OPTIONAL DOCUMENTS	
Investigator Brochure (s)	
Device Manual(s)	
eBridge Smartform	The Approved IRB Submission may be converted to a pdf document and uploaded into OnCore.
IRB Approval Letter	
Reportable Event Acknowledgement Letter	
Other Documents 1 - 5	If there are other documents you wish to upload, select “other documents”.

**Note: It is not possible to select One document “Type” for multiple documents. For example, if a study has 3 Consents (Treatment, Screening, Tissue) you would select Consent 1 for the Treatment, Consent 2 for Screening and Consent 3 for Tissue. If ONLY the Tissue Consent is modified via a Protocol Amendment six months later, you would record this review and select Consent 3 as the “Type” to upload the current Tissue Consent. It’s critical you select the same “Type” for updated documents. This assures the most current version appears in the Document Search.**



## Uploading IRB documents in the Details Tab

The screenshot shows the 'Details' tab in the IRB review system. A callout box points to the 'Type' dropdown menu, listing options such as 'Consent 1', 'Consent 2', 'Device Manual 1', and 'eBridge AME Smartform (pdf)'. Another callout box explains the 'Description' field: 'Description: Enter the File Name. This shows up in the IRB review tab summary'. A third callout box explains the 'Comments' field: 'Comments: Enter additional comments, for example "Tissue Consent"'. A fourth callout box explains the 'Version Date' field: 'Version Date: Enter the Stamped Date for Consents and the Date of IRB approval for other documents (usually the same)'. A large note box states: 'Note: OnCore's Version Date (Date of IRB Approval) may be different than the actual document's Version Date. To avoid confusion, a best practice is to include the DOCUMENT version date in the file name.' The interface also shows buttons for 'Add', 'Save', and 'Cancel', and a 'Next Page' arrow.

**Description:** Enter the File Name. This shows up in the IRB review tab summary

**Comments:** Enter additional comments, for example "Tissue Consent"

**Select the document type**

Type: Consent 1, Consent 2, Consent 3 etc., Device Manual 1, Device Manual 2, eBridge AME Smartform (pdf), Etc. – See Definitions Below

**Version Date:** Enter the Stamped Date for Consents and the Date of IRB approval for other documents (usually the same)

**Note:** OnCore's Version Date (Date of IRB Approval) may be different than the actual document's Version Date. To avoid confusion, a best practice is to include the DOCUMENT version date in the file name.

Next Page



**Details (1)** | Reviewers (0) | Communications (0) | Notes

N/A unless:  
 1) This is a multi-site study  
 2) MCW is the coordinating site  
 3) Other institution's IRB must

Reconsent Required?: When an amendment or CPR results an updated consent form, a checkbox will appear and can be used to indicate a reconsent requirement for enrolled subjects.

Details							Add	Select Previous Details/Docs
Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
<a href="#">Consent 1</a>			01/09/2017	ICFPRO100001-XYZ- 12.12.2016	Subject Treatment Consent	<input type="checkbox"/>	N/A	<input type="checkbox"/>

Attach a [File](#) or [URL](#)

Click the [File](#) hyperlink to upload "Consent 1"

For the Initial Submission, if "Approved with Modifications, select Create Follow-up Review. If selected, the "Submit Date" in the Review Information defaults to the original. Do not change this.

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



## Releasing Documents and Document Search

The screenshot displays the 'Details' tab for a document. The table below shows the document's metadata:

Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
Consent 1			01/09/2017	ICFPRO100001-XYZ- 12.12.2016	Subject Treatment Consent	<input type="checkbox"/>	N/A	<input type="checkbox"/>

Callout boxes provide the following information:

- Top Callout:** It's important the Version Date relates to the IRB Approval Date and NOT the actual version date of the document. Searching for current consents and other IRB-approved document is done through *Protocols>Document Search*. Only documents with the most current version date will appear. Ex: If Consent 1 had previous versions, only the 12.26.13 version would appear in the Document Search results.
- Bottom Left Callout:** "Consent 1" has been uploaded.
- Bottom Right Callout:** Check "Release" to make the document(s) available in OnCore. Consents are ONLY available in *Protocols>Document Search*. Other Released IRB documents are available in both *Protocols>Document Search* AND the *PC Console>Documents/Info>Attachments* page.

