

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

The screenshot shows the 'Review Information' section of the IRB Review Tab. It includes fields for Review Date, Submit Date, Action Date, Expiration Date, Committee, Review Reason, Review Type, and Review No. Several callout boxes provide instructions: one for the Review Date field, one for the Action and Expiration Dates, one for the Review No. field, and a general note about the Review Date and Action Date. The interface also shows 'Protocol Status: IRB INITIAL APPROV.' and 'IRB Expiration: 02/28/20'.

**Protocol Status: IRB INITIAL APPROV.**  
**IRB Expiration: 02/28/20**

**Review Information**

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

**Enter the "Received by IRB Office" date from eBridge. Do NOT enter the "Submitted Application" date.**

**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**

Abstain Votes  
Institution  
Details (0) Reviewers (0) Communications (0) Notes  
Details  
Amend- Reconsent



## 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 of the IRB review system. It features a table with columns for 'Type', 'Amendment No.', 'Received Date', 'Version Date', 'Description', 'Comments', 'Global?', 'Reconsent Required?', and 'Delete?'. A callout box points to the 'Description' column with the text: 'Description: Enter the File Name. This shows up in the IRB review tab summary'. Another callout points to the 'Comments' column: 'Comments: Enter additional comments, for example "Tissue Consent"'. A third callout points to the 'Version Date' column: 'Version Date: Enter the Stamped Date for Consents and the Date of IRB approval for other documents (usually the same)'. A fourth callout points to the 'Type' dropdown menu, which is open to show options like 'Consent 1', 'Consent 2', 'Consent 3 etc.', 'Device Manual 1', 'Device Manual 2', 'eBridge AME Smartform (pdf)', and 'Etc. - See Definitions Below'. A 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 includes buttons for 'Add', 'Save', 'Cancel', 'Clear', and 'Close'.

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

**Details** Add Select Previous Details/Docs

Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
<a href="#">Consent 1</a>			05/10/2015	ICF-PRO10001-XYZ-4.11.201.6.pdf	Subject Treatment Consent	<input type="checkbox"/>	N/A	<input type="checkbox"/>

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

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

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.

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.

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



## Releasing Documents and Document Search

4000 character(s) remaining

Yes Votes  No Votes

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

Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
Consent 1			12/26/2013	ICF-Treatment Consent v1.0 Nov2013				<input type="checkbox"/>

ICF-Treatment Consent v1.0 Nov2013.docx Release:

**Annotations:**

- 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.
- 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.
- "Consent 1" has been uploaded.

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

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