

MCW uses eBridge to electronically track Human Research submissions. There is no electronic interface between eBridge and OnCore. To minimize redundancy between the two systems, the following is a list of the minimum required IRB reviews to be entered in OnCore and Documents to be uploaded. Depending on the functionality you are using, you may wish to document additional IRB reviews such as Reportable Events.

## Required IRB Reviews

Review Type	
<i>Required IRB Reviews</i>	
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.
<i>Optional IRB Reviews</i>	
Non-protocol Amendments	
Reportable Events	If a SAE or other adverse event/deviation is recorded in OnCore, it is recommended the IRB acknowledgement also be recorded.



## Required IRB Documents

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

### IRB Documents to Upload

<i>REQUIRED DOCUMENTS</i>	
Consent 1	Consent 1 is the Study’s Main Consent. All stamped, approved consents must be uploaded.
Consent 2-5 if applicable	For additional Consents (e.g. Blood, Banking, Screening etc.)
Protocol	All versions including the initial submission along with subsequent amendments
IRB Approval Letters	IRB Initial Application; subsequent CPR and change of protocol amendment Approval Letters
<i>OPTIONAL DOCUMENTS</i>	
Investigator Brochure (s)	
Device Manual(s)	
eBridge Smartform	The Approved IRB Submission may be converted to a pdf document and uploaded into OnCore.
Reportable Event Acknowledgement Letter	If a SAE RE is recorded in OnCore, it’s recommended the corresponding RE acknowledgement letter be uploaded.
Other Documents 1 - 5	If there are other documents you wish to upload, select “other documents” and add a description.
SAE Documentation	If a SAE RE is recorded in OnCore, it’s recommended the corresponding SAE documentation be uploaded.

**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.**



## Recording an IRB Review in the Review Information section

**Update IRB Review** ?

Protocol No: **SCREENSHOTS** Library: **MCW General** PI: \_\_\_\_\_ Sponsor: \_\_\_\_\_  
Protocol \_\_\_\_\_ 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.: [ ]

Abstain Votes: [ ] Institut: \_\_\_\_\_

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

**Callouts:**

- 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**



## Uploading IRB documents in the Details Tab

The screenshot shows the 'Details' tab in the IRB system. A callout box points to the 'Type' dropdown menu, which lists document types such as 'Consent 1', 'Consent 2', 'Consent 3 etc.', 'Device Manual 1', 'Device Manual 2', 'eBridge AME Smartform (pdf)', and 'Etc. - See Definitions Below'. Another callout box points to the 'Description' field, stating: 'Description: Enter the File Name. This shows up in the IRB review tab summary'. A third callout box points to the 'Comments' field, stating: 'Comments: Enter additional comments, for example "Tissue Consent"'. A fourth callout box points to the 'Version Date' field, stating: 'Version Date: Enter the Stamped Date for Consents and the Date of IRB approval for other documents (usually the same)'. A fifth callout box points to the 'Save' button, containing a note: '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', 'Select Previous Details/Docs', 'Global?', 'Reconsent Required?', 'Delete?', 'Save', and 'Cancel'. A large curved arrow at the bottom right points to the text 'Next Page'.



N/A unless:

- 1) This is a multi-site study
- 2) MCW is the coordinating site
- 3) Other institution's IRB must approve this amendment.

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

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>			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 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.
- Bottom-Left Callout:** "Consent 1" has been uploaded.

