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 | |
|----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Required IRB | Reviews |
| 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. |
| Optional IRB | Reviews |
| 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

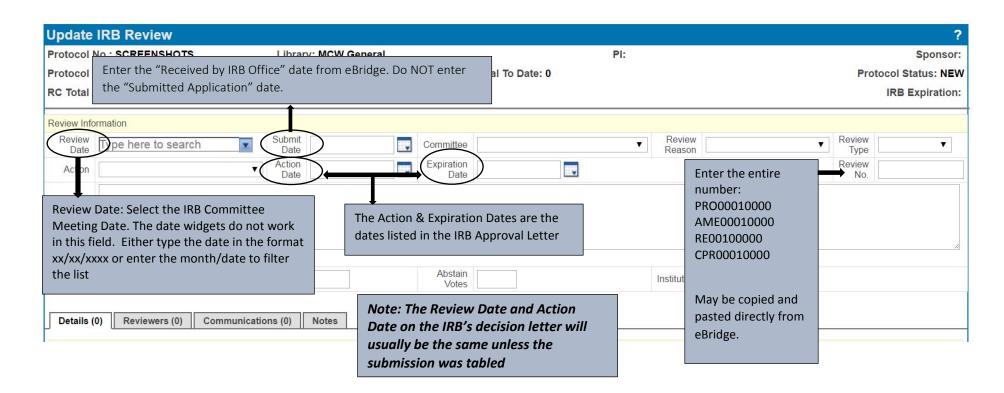
| REQUIRED DOCUMENTS | | | | | | |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------------|--|--|--|--|--|
| Consent 1 | Consent 1 is the Study's Main Consent. All stamped, approved consents must be uploaded. | | | | | |
| 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 | | | | | |
| 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. | | | | | |
| 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 decription. | | | | | |
| 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 <u>3</u> 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.

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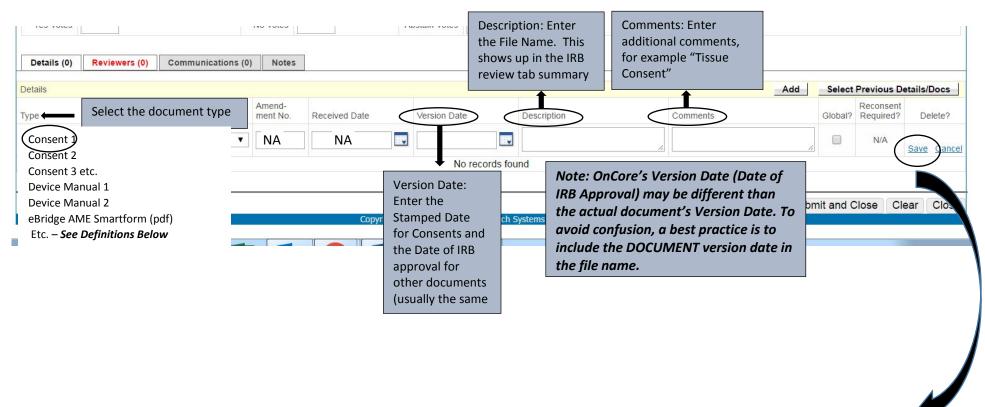
Recording an IRB Review in the Review Information section







Uploading IRB documents in the Details Tab



Next Page

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| Details (1) | Reviewers (0) | Communications (0) | Notes | 1 | | 2) N si 3) O | nis is a multi-site study ICW is the coordinating | 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 | | | | | | | | Add Select Previous Details/Docs |
| Туре | | nend- ent No. Received Date | | Version Date | Description | | Comments | Global? Reconsent Required? Delete? |
| Consent 1 Attacha File | OMUDI | Click the <u>File</u> hyperlin to upload "Consent 1 | | 01/09/2017 | ICFPRO100001-XY | Z- 12.12.2016 | Subject Treatment Consent | |
| | | | ct Creat bmit Da | e Follow-up Review. te" in the Review Info | | Agenda Createms, All rionts re | te Follow-Up Review Subn | nit Submit and Close Clear Close |

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Releasing Documents and Document Search

| Details (1) Reviewer | rs (0) Communica | ations (0) Notes | | late of the document. Searching f done through <i>Protocols>Documen</i> | ates to the IRB Approval Date and or current consents and other IRB <i>t Search</i> . Only documents with th had previous versions, only the 12 soults. | B-approved do e most currer | ocument is nt version | |
|----------------------|------------------------|------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------------|----------|
| Туре | Amend- ment No. Rec | ceived Date | Version Date | Description | Comments | Global? | Reconsent Required? | Delete? |
| Consent 1 | | | 01/09/2017 | ICFPRO100001-XYZ- 12.12.2016 | Subject Treatment Consent | | N/A | |
| CEPRO100001-XYZ-12 | | lease: | Consent Other R | Release" to make the document(s s are ONLY available in <i>Protocols></i> eleased IRB documents are available PC Console>Documents/Info>Att | Document Search. ole in both Protocols>Document S | earch hd Cl | lose Clea | ar Close |

