IRB Review Tab Details

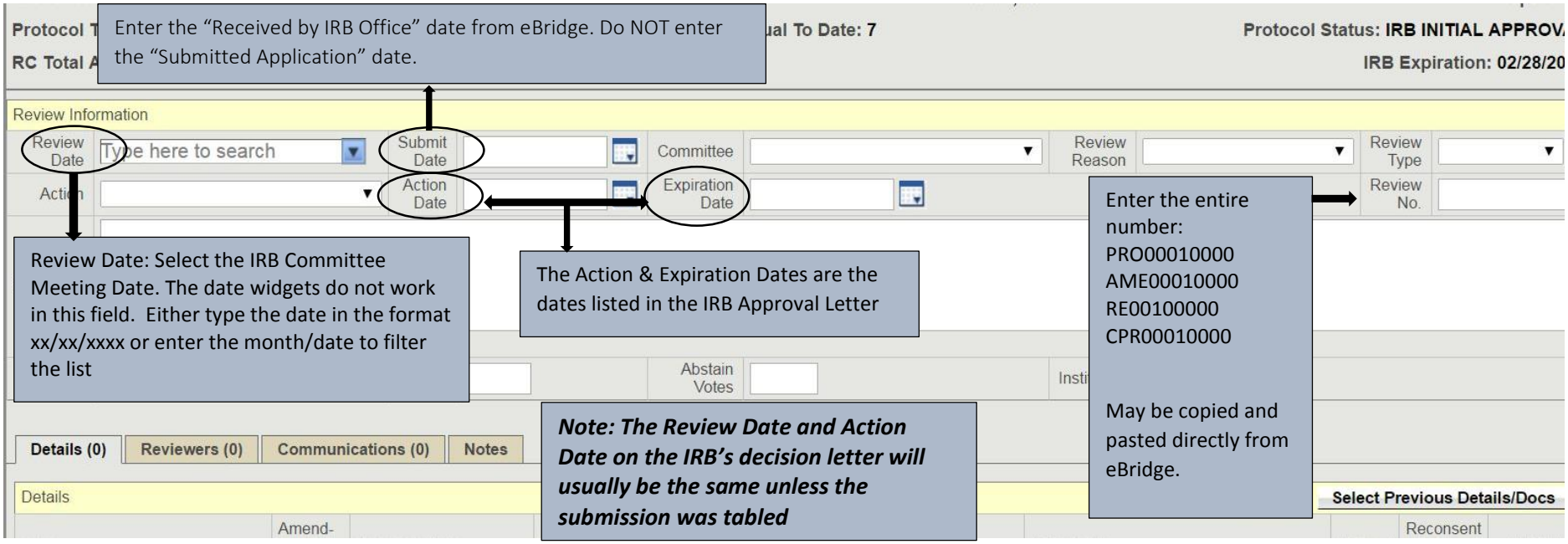
MCW uses eBridge to electronically track Human Research submissions. Currently, there is no electronic interface between eBridge and OnCore. To minimize the redundancy between the two systems, the following is a list of the minimum required IRB reviews to be documented in OnCore to assure the most current 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
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	

IRB Review Tab Details

Recording an IRB Review in the Review Information section



IRB Documents

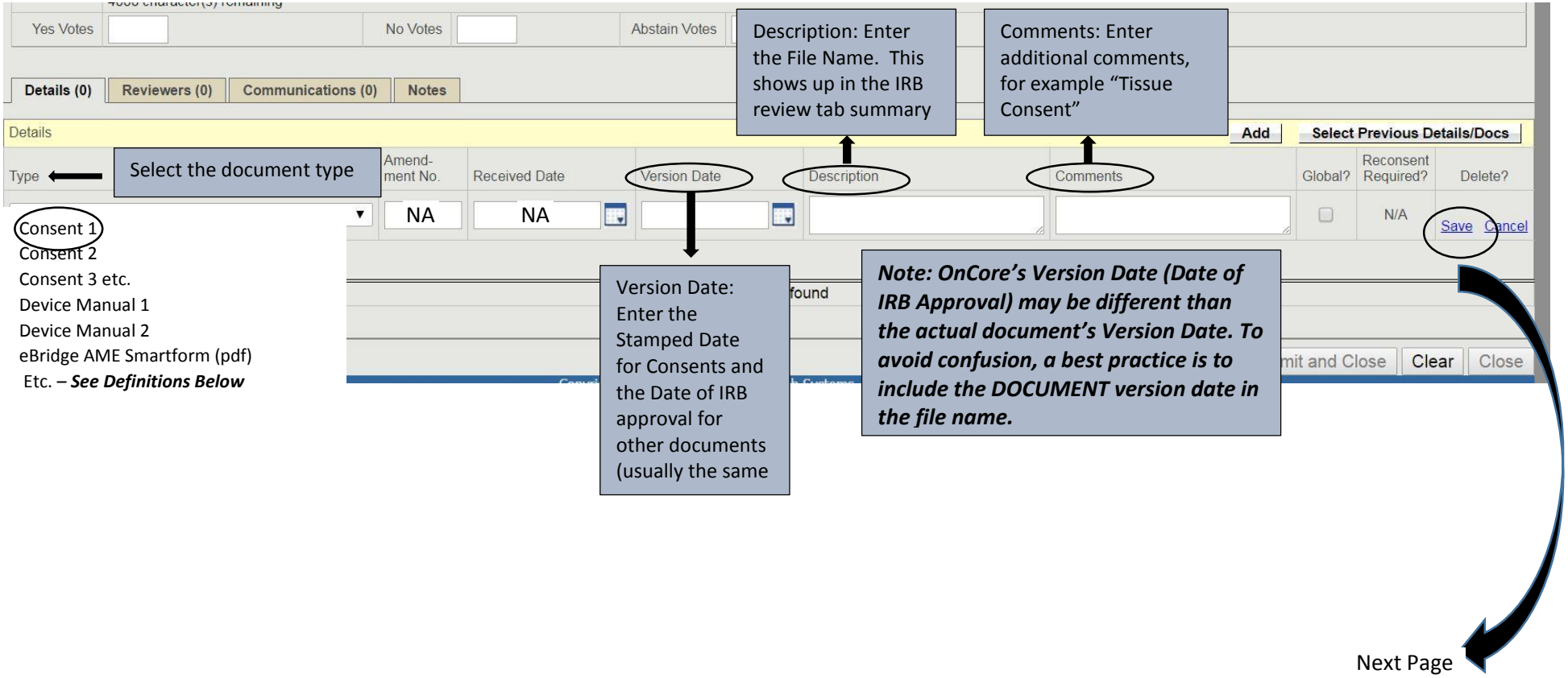
The Details Tab is where IRB-related documents are uploaded by clicking “Add”.

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



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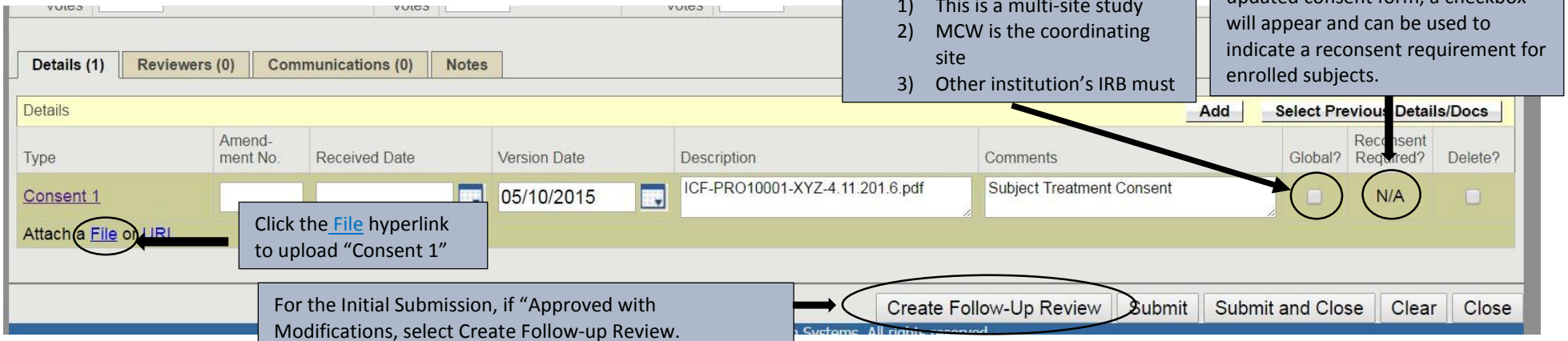
IRB Review Tab Details



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.

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.

Releasing Documents and Document Search