IRB Review Tab Requirements

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

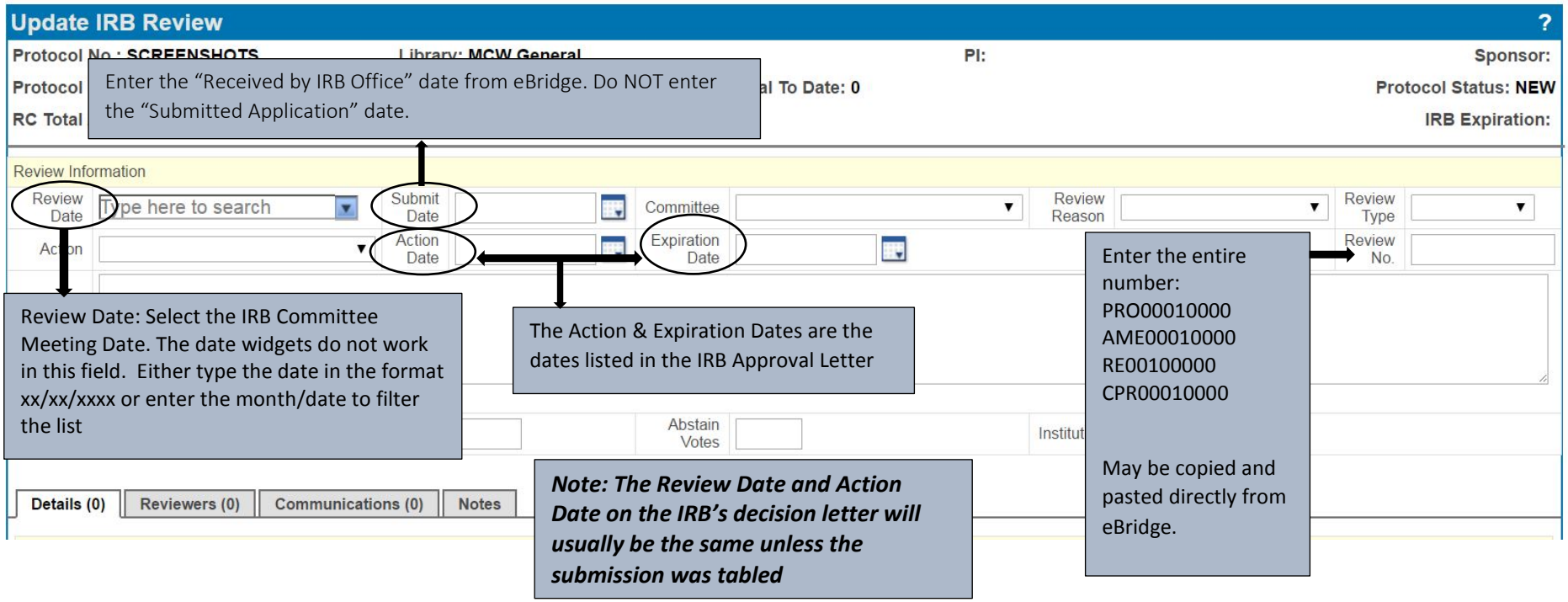
The Details Tab is where IRB-related documents are uploaded by clicking “Add”.

IRB Documents to Upload

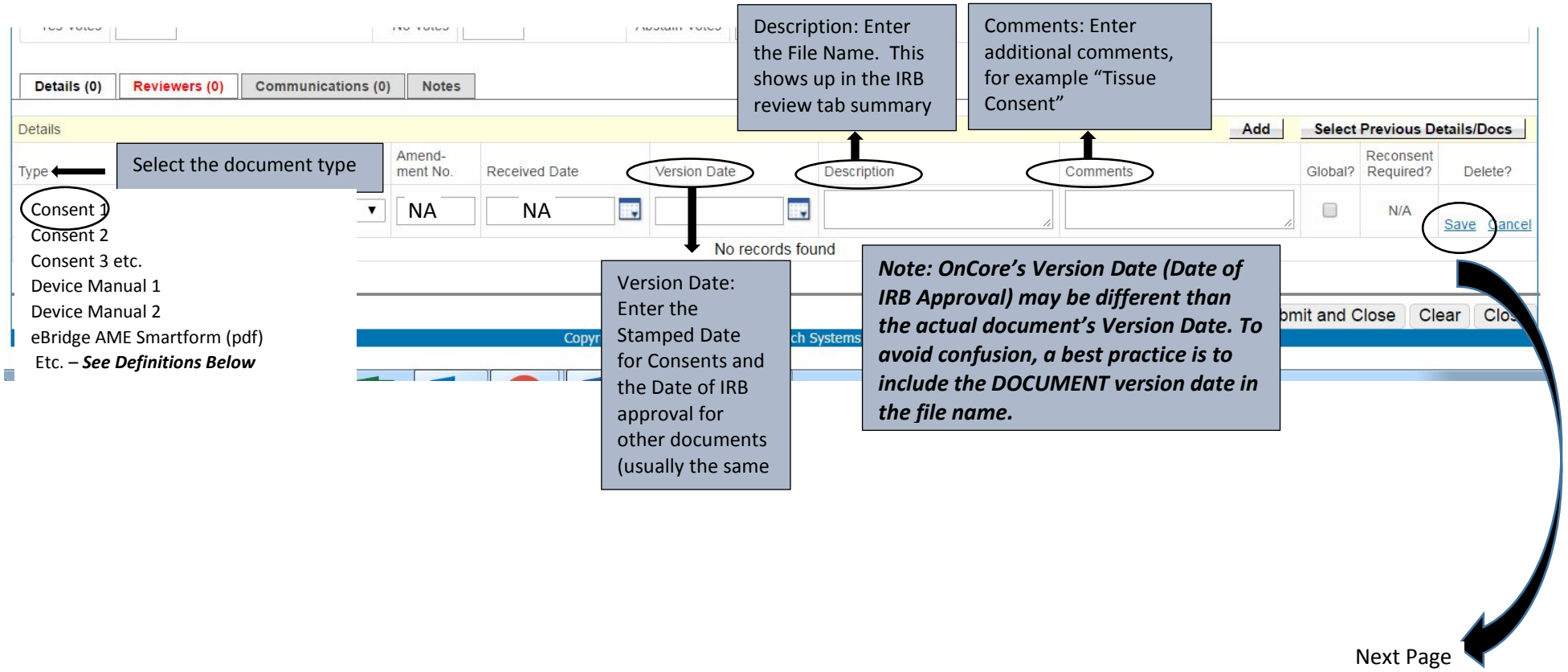
REQUIRED DOCUMENTS	
Consent 1	Consent 1 is the Study’s Main Consent. All stamped, approved consents must be uploaded.
Consent 2-5 if applicable	For additional Consents (e.g. Blood, Banking, Screening etc.)
Protocol	All versions including the initial submission along with subsequent amendments
IRB Approval 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 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.

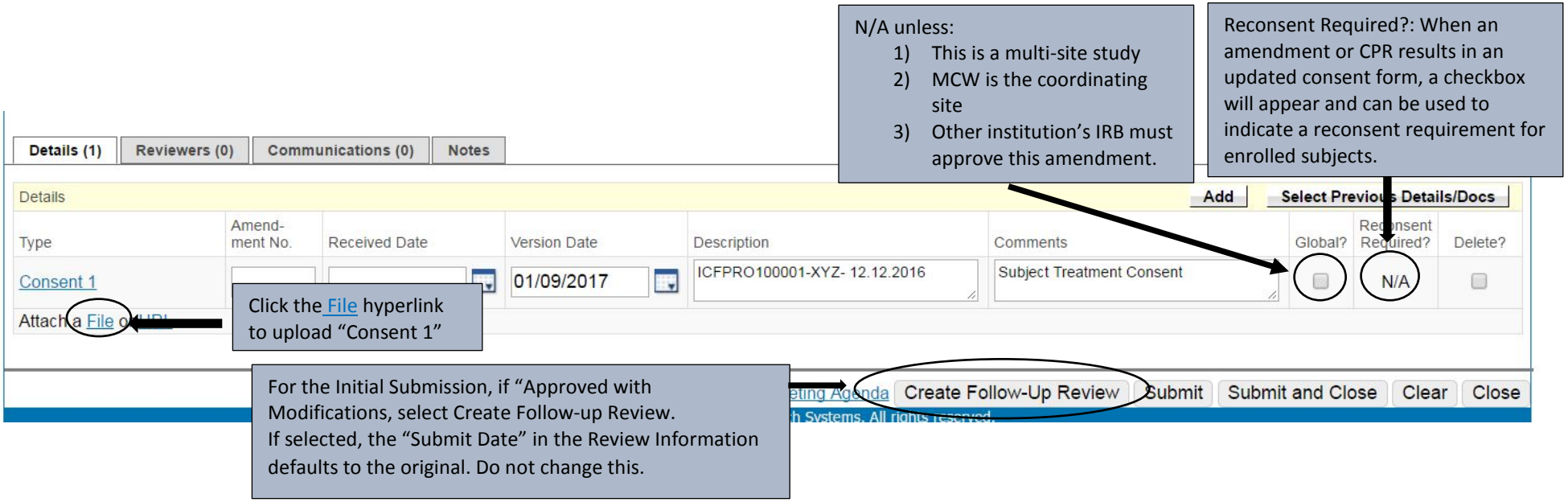
Recording an IRB Review in the Review Information section



Uploading IRB documents in the Details Tab



IRB Review Tab Requirements



Releasing Documents and Document Search