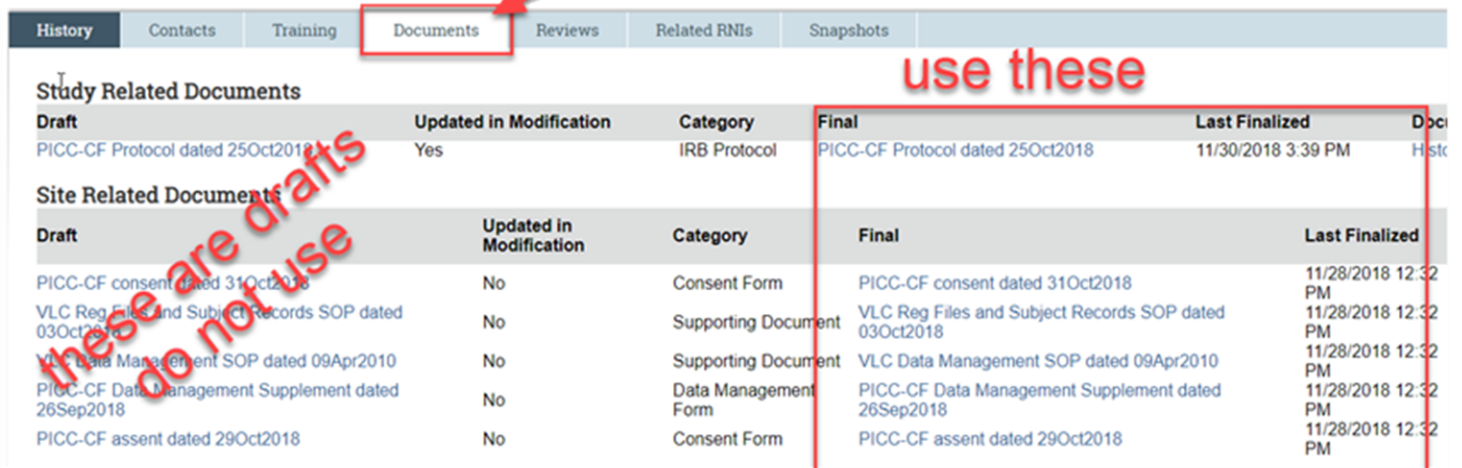


Tip Sheet 2: Clean-up Modifications & Related Items

- We have received approximately 350 submissions and have gathered additional tips for quicker review and approval of your **clean-up modifications**.
 - If you have previously informed the IRB that you are no longer enrolling subjects, it is not necessary to attach the last IRB-approved consent form. However, the last approved protocol is required.
 - Reminder that you should not be changing your protocol as part of the clean-up modification submission.
 - Remember when you are done completing your clean up modification to hit the “**submit**” button on the far left of the screen, otherwise we cannot act on it.
- To locate your currently approved documents go here. This is a model example as there are dates included in the document names. This is very helpful when there are multiple documents



use these

Study Related Documents						
Draft	Updated in Modification	Category	Final	Last Finalized	Doc	
PICC-CF Protocol dated 25Oct2018	Yes	IRB Protocol	PICC-CF Protocol dated 25Oct2018	11/30/2018 3:39 PM	Hist	
Site Related Documents						
Draft	Updated in Modification	Category	Final	Last Finalized		
PICC-CF consent dated 31Oct2018	No	Consent Form	PICC-CF consent dated 31Oct2018	11/28/2018 12:32 PM		
VLC Reg Files and Subject Records SOP dated 03Oct2018	No	Supporting Document	VLC Reg Files and Subject Records SOP dated 03Oct2018	11/28/2018 12:32 PM		
VLC Data Management SOP dated 09Apr2010	No	Supporting Document	VLC Data Management SOP dated 09Apr2010	11/28/2018 12:32 PM		
PICC-CF Data Management Supplement dated 26Sep2018	No	Data Management Form	PICC-CF Data Management Supplement dated 26Sep2018	11/28/2018 12:32 PM		
PICC-CF assent dated 29Oct2018	No	Consent Form	PICC-CF assent dated 29Oct2018	11/28/2018 12:32 PM		

- You may have noticed on the **training page** the note “no training on file.” CITI Training Records will be loaded into UVMClick – IRB in December. Once that is complete, you will see key personnel training documentation in this area. Until that data is coming into the system, we will continue to maintain the [tutorial completion](#) page on our website for reference.



Role on Study	Registration Date	Date Report Complete
Principal Investigator	no training on file	
Team Member	no training on file	
Team Member	no training on file	
Team Member	no training on file	
Team Member	no training on file	
Team Member	no training on file	

these will all be filled in once CITI data is pulled in

- When submitting **key personnel changes/study team member modifications**, ensure that you include in the summary box of the SMARTForm a statement about who is being added and who is being removed from the study. This information is pulled into your approval document.

Modification Information

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• Summarize the modifications:
 Study Team Update: Add Johannes Nunnrik, Scott Perrapato, Janet Ely, Megan Hinton, Jamie Lewis, Jennifer Dulin, Kaley Dickie, Hannah Walker and Anthony Minichiello

🔔 The IRB expects to see a description of the protocol changes such as:

- Study Team Member changes

- Newly approved protocols, consents, and information sheets** will have a new system-generated stamp at the top of the page (see below). You may wish to allow some room at the top of your these documents to accommodate this new stamp. Note: Continue to use **previously approved consent documents with the IRB stamp on the last page** of the document until you have a consent modification. Then we will apply the system-generated stamp going forward.

Human Subjects Research Protocol

PROTOCOL SUMMARY

Title:

Protocol Ver
(required for
modification)

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