



UVMClick Website UVMClick Login https://www.uvm.edu/ovpr/uvmclick https://irb.connect.uvm.edu/IRB Email Support Phone Support UVMClick@uvm.edu (802) 656-5040

Tip Sheet 6: Study Numbers, Titles, Ancillary Reviews, Clean-up Modifications, Approved Documents

Study Numbers Explained

Protocols created in InfoEd maintain their originally assigned numbers (e.g. M12-134, 18-060) until those protocols are closed. New protocols submitted through Click all have a prefix of STUDY... (e.g. STUDY000020.) Studies for which UVM IRB relies on another IRB is prefixed by SITE... (e.g. SITE000013.) You should continue to use the number assigned for your protocols at time of initial review despite which system they began in.

Modifications are prefixed by "MOD" and reportable new information submissions are prefixed by "RNI".

EPIC and Financial Edge use these same numbering conventions, so always reference the number that has been assigned in the IRB system.

Study Titles

While the system requires you to insert both a full and a short title, we really need to have you insert the full title of the protocol in both places. The short titles, which are often times acronyms, can not be used in formal IRB correspondence and the acronyms do not provide enough information at a glance to determine what the protocol may involve. There are multiple stakeholders across both institutions that reference the Click records, therefore the title of the protocol must be meaningful. Going forward please always insert the full protocol title in both places in the Smart form. If you wish to include an acronym at the end of a title, you are welcome to do so.

UVMClick Institutional Ancillary Reviews

The Click system has functionality that allows the investigator and or IRB analysts to refer a submission to an ancillary reviewer. In some cases, the completion of an ancillary review is required prior to release of IRB approval. The system will stop the IRB analyst from releasing approval in those instances. If you know that you need to obtain prior ancillary review, the investigator or the investigator's proxy, should assign that ancillary review once you are ready to submit (guide here). That will notify the appropriate department/person of your submission so that they are able to review for their specific requirements. If you fail to do this at time of

submission and your submission indicates that one of these ancillary reviews applies, the IRB analysts will send it on your behalf.

You may check for the status of a required ancillary review on the Reviews tab. As of June 1, this tab will also be available on the modifications page.



<u>Clean up Mods</u>

Our Click reports indicate that there are approximately 200 protocols that will be required to submit a clean-up mod prior to their next continuing review. If you have not done so to date, please submit a clean-up mod now so that processing a continuing review does not get held up awaiting a clean up modification submission. <u>Instructions</u>

Approved Documents

To find your approved documents go here.

Impcuments	Follow-on Submissions	Reviews	Snapshots	Conversion Documents		
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	Category		Final			
.7.pdf	IRB Protocol	PEDIA	PEDIATRIC MIGRAINE REGISTRY PROTOCOL Version 0.7.pdf			
	Category		Final			
	Consent Form Supporting Docume	ent	Pediatric Migraine Registry ICF 28Mar2019.pdf MigrnX Privacy Statement.pdf Research Data Management and Security Plan 3.28.2019.pdf Study Info Sheet MigrnX Mobile Application Screenshots.pdf PedMIDAS Questionnaire pdf			
docx	Data Management Information Sheet	Form				
	Supporting Docume	ent				
Questionnaire			Headache and Migraine History Questionnaire.pdf			