Tip Sheet 5: Navigating UVMClick and Other Information

1. Navigating Tips

• How do I find the parent study when I am in a modification?
  From the modification page, use the “breadcrumbs” feature to find your way back to the parent.

  Click here, then here on the title

• How do I get back to a modification from the parent study?
  On the parent study page, click on Follow-on Submissions. There you will see all your previous submissions. From the state you can tell if you have not submitted it yet (pre-submission), whether RPO has it (pre-review), or if it is approved.
2. Data Safety and Monitoring Reports or Non-Risk Safety Reports
Sponsors look for a descriptive comment about what was reviewed by the IRB. Below is a model example of a description that you would put in the summary of the modification for all DSMB and Non-Risk Safety Report.

Modification Information

Study enrollment status (if applicable, check all that apply):
Subjects are currently enrolled

Notification of subjects: (if applicable, check all that apply)
There are no items to display

* Summarize the modifications:
Submission includes: 1) QP Excel’s 12 Month Interim Post Approval Registry Report dated 01 November 2018 and 2) QP Excel’s MPP Sub-Study 18 Month Post Approval Registry Report dated 02 November 2018

3. New Protocol and Clarification Responses
There are two different sections within the SMART form to upload documents. It is important that you upload the correct documents in each section. Below are the two areas:

Protocol is uploaded under Study, #11.
Consent and Other Attachments are uploaded under Local Site Documents, #1, 2, &3.

Local Site Documents

4. Updating/Revising Your Protocol Document
When you need to revise your protocol, please make sure that you are “updating” the protocol document that is already present in the system. There should only be one protocol document in the system. When you click “update” the system will version the document behind the scenes. When you update, you should make sure that you include the version date on both the protocol document itself as well as the document name. This will ensure consistency.

5. Printing Your Approved Documents
In follow up to our last tip sheet regarding printing approved documents, the stamp is set very high on the page to avoid overwriting text within the document. We are looking into placing the stamp a little lower on the page, so we suggest that you allow for a 1-inch margin at the top of your documents. Hopefully this should resolve most printing issues. Use of the stamped versions of consents and information sheets is required.