

## Tip Sheet 4: Clean-up Modifications & Additional Updates

### 1. Clean-up Modifications

Exempt protocols do not require a clean-up modification unless you plan to submit an amendment to change the scope of your exemption.

### 2. Email Addresses Receiving Click Notices

The email addresses assigned to you are fed into the Click system on a nightly basis from both UVM and UVMHC directories. The [uvmhealth.org](http://uvmhealth.org) addresses override the [uvm.org](http://uvm.org) addresses for those employees with dual appointments. We are working with the hospital to determine if specific email from Click can be forwarded to UVM and if so, how to properly set that up. Once that has been determined we will communicate the outcome.

### 3. Continuing Review

#### Continuing Review / Study Closure Information

Specify enrollment totals:

	Subjects Enrolled	Total	Stick List Approval
At this investigator's site:	21	21	21
Study-wide:	21	21	21
* Number of locally signed consents:	21		
* Number of local subjects withdrawn, discontinued, or died during the study after being enrolled:	0		
* Number of local subjects who completed the study:	0		

**This is a Click question - We do not expect you to track down the study-wide enrollment totals. Enter the local total enrollment here.**

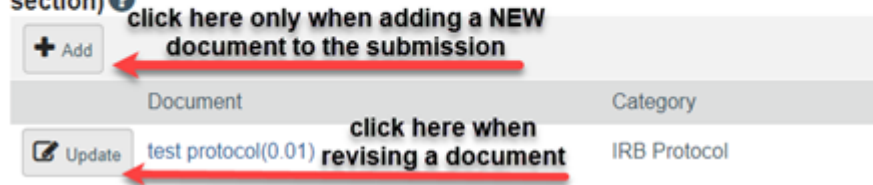
**this is how many enrollments since the last continuing review**

### 4. Clarification Responses

When your response to the IRB requires a revised document, please make sure that you are “updating” a document that is already present in the system and not adding a new one. The system has functionality for us to compare versions of documents as long as they have been “updated versus added.”

Your response may also require submission of a new document and that is when you would “add” versus edit a document.

12. \* Attach the protocol:  
(e.g. industry protocol, human subjects protocol, exempt form, or not hum. section) ?



The screenshot shows a document management interface. At the top left is a '+ Add' button. Below it is a table with two columns: 'Document' and 'Category'. The first row in the table has 'test protocol(0.01)' in the 'Document' column and 'IRB Protocol' in the 'Category' column. To the left of the table is an 'Update' button. Red arrows point from text annotations to the 'Add' button and the 'Update' button.

**click here only when adding a NEW document to the submission**

**click here when revising a document**

## 5. Printing Your Approved Documents

In tipsheet #2 we discussed the new system-generated approval stamp. This stamp is located at the top of each page with a minimal margin. We recommend that you try printing one page first to see if the stamp appears, as we have heard from some of you that the stamp is not printing on the materials. You may need to change your printer settings to allow for narrow margins. Use of the stamped versions of consents and information sheets is required.

