IRB News – 7.25.17: HSERA Confirmation Page Update

Currently when creating a new submission (Modification, Deviation, Exception, or Reportable Event) for an approved study, the documents that were attached to the most recent prior submission remain attached to the Confirmation page. It is up to the submitter to either remove those attachments or allow them to remain attached as older documents. These documents can be removed from the draft submission by clicking the red “X” buttons to the right of each file name. For many study teams there may be dozens of documents shown for each document type depending on the age and design of the study.

The screen shot below demonstrates a modest example of this function on the confirmation page in a modification submission. Even though this new modification is being created in June 2017, two additional forms that were submitted back in 2014 are shown as attached to the item.

- Questionnaires, inventories surveys, diaries, personality tests, quality of life assessment or other surveys or instruments, consent and recruitment scripts.
  - Exception: Widely recognized, accepted, standard tests in a given field do not need to be submitted for review.

- All recruitment materials, including advertisements, brochures, letters to patients, transcripts of all broadcast materials

Additional forms or documents

- If you have additional forms or documents to attach to this protocol, please upload them here

The following documents are currently attached to this item:

- Additional forms (hansoncompletionreport.pdf)  Date uploaded: 03/06/2014 02:35:55 PM
- Additional forms (091514bloodcultureicutransfer.doc.docx)  Date uploaded: 09/15/2014 09:39:59 AM

Upload form

Modification Summary

There are no documents attached for this item.

Upload form

By clicking 'I accept' below, you are electronically signing the following statements and submitting your application:

1. I have read and understood the University of Pennsylvania guidelines concerning human subjects projects and protocols.
2. I certify that the information provided in this submission is complete and correct to the best of my knowledge.

Back  I accept
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With the update to HSERA, when you create the submission it will contain no attached documents on the confirmation page or on any of the pages within the application. The Confirmation page will be blank (unless you have attached a document on a previous page when drafting the current submission like in the example below). Any documents related to your modification must be attached by the submitter. You should only attach new documents to be reviewed as part of the current submission. Older, previously approved documents, should only be attached if you feel the content of those documents is essential to the IRB’s review of the current submission.

Modification Form - Submitter’s assurance

Documents attached within the application

Vulnerable Populations (hsерatestenvironmentlink.docx) Date uploaded: 06/23/2017 12:48:51 PM

Additional forms or documents

- [ ] Cover Letter (with additional information that may help in the review)

There are no documents attached for this item.

Upload form

- [ ] Full sponsor’s protocol
  Please note: If you do not have a full/clinical protocol for upload, and are required to submit one with your application, or prefer to attach a protocol document, the Office of Clinical Research (OCR) provides templates located on their website at [http://www.med.upenn.edu/ocr/](http://www.med.upenn.edu/ocr/).

- [ ] Grant Application (minus the appendices & budget information, for federally-funded studies, e.g. NIH, CDC, DOD)

- [ ] Performance site approvals for sites other than Penn (this does not apply to other participating sites which have their own IRB.)

- [ ] Informed consent form (and parental permission/assent form for research involving children)

- [ ] HIPAA Authorization or Waiver (if applicable)

- [ ] Investigator’s brochure/product labeling (for research involving investigational drugs or devices)

All previously submitted documents (including documents that were attached to other pages of HSERA) will still be available in HSERA. To access them, study teams will need to refer to the actual submission they were originally attached to by using the unique confirmation code in the submission history search field.