

The University of Louisville IRB is changing the IRB approval stamp on informed consent documents (this includes assents and preambles).

Any approval sent on or after April 1, 2018 where consent forms will be stamped will no longer have an expiration date on the stamp. The consent form will be stamped with an approval date only. The consent will expire if the study lapses in IRB approval. Enrollment cannot take place if a study lapses in approval.

When you complete a Continuing Review Application in iRIS, It's local policy for the consent documents (if the study is open to enrollment) and the protocol to be attached to the continuing review application for the IRB to review.

Please use the following steps to pull your current approved documents into the continuing review application from iRIS rather than doing an external document upload.

Section view of the Form

Entire view of the Form

- Continuing Review Application
- Expedited Review
- Study Type
- Research Activities
- Compliance
- Conflict of Interest
- Additional Information
- Attachments**

For Continuing Reviews
Use "Select or Revise Existing" to attach your current approved consent documents as well as your current protocol

8.0 Attachments

8.1

When possible, attach Word documents instead of PDFs

Please attach (if applicable):

- Current Informed Consent documents
- One PDF file containing the scanned versions of the last 5 signed consents, assents and research authorizations should be attached here.

Detach	Version	Title	Category	Language	Expiration
No Consent(s) have been attached to this form.					

Please attach (if applicable):

- Current HIPAA documents (clean word document without prior year stamp)
- Current Protocol
- Recent Literature
- Relevant Findings
- FDA Related Documents
- Monitoring Reports
- Data and Safety Monitoring Board Reports
- Any other documents related to this Continuing Review

Detach	Version	Title	Category	Expiration Date	Doc
No Document(s) have been attached to this form.					

Department: U of L - 27 - Exec VPR - Human Studies
Navigation:

Select Existing or Create Revised Study Consent

Select Category: --none--
Version #: .
Version Date: between
Consent Outcome: --none--

Title:
Search level: Top All
Expiration Date: between

1 result(s) found...

Select	Show all Versions	Edit	Delete	Version	Version Date	Title	Language	Expiration Date	Consent Outcome	Checked Out By	View Document	Create Revision
<input checked="" type="checkbox"/>				1.0	07/12/2017	17.0514 2014-07-01 old old consent	English	07/02/2018	Approved		31.65 KB	

Click to select the document you want to add to the submission

Once selected, close the form

The document now shows as an attachment on the continuing review application form.

Section view of the Form | Entire view of the Form

Continuing Review Application
Study Type
Research Activities
Compliance
Conflict of Interest
Additional Information
Attachments

7.0 Attachments

7.1 Please attach (if applicable):

- Current Informed Consent and HIPAA documents (clean word document without prior year stamp)
- Current Protocol
- One PDF file containing the scanned versions of the last 5 signed consents, assents and research authorizations
- Recent Literature
- Relevant Findings
- FDA Related Documents
- Monitoring Reports
- Data and Safety Monitoring Board Reports
- Any other documents related to this Continuing Review

Detach	Version	Title	Category	Expiration Date	Document Outcome
No Document(s) have been attached to this form.					

No Application has been associated with this submission.

7.2 Please attach consents.

Detach	Version	Title	Category	Language	Expiration Date	Consent Outcome
<input checked="" type="checkbox"/>	1.0	17.0514 2014-07-01 old old consent		English	07/02/2018	Approved

The document will show here