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.
Adding Existing iRIS Documents to a Continuing Review in iRIS

Human Subjects Protection Program Office
MedCenter One
501 E. Broadway, Suite 200
Louisville KY 40202-1798 P: 502-852-5188
Service Acct: hsppofc@louisville.edu

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

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

The document will show here