

	HUMAN SUBJECTS PROTECTION PROGRAM	Location Changes and the IRB	Human Subjects Protection Program Office MedCenter One 501 E. Broadway, Suite 200 Louisville KY 40202-1798 P: 502-852-5188 Service Acct: hspofc@louisville.edu
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If during the course of the study the physical location of the department or clinic moves, study documents must be revised and subjects must be notified. The IRB recommends giving all patients in clinic (regardless if they are on a research study) an announcement sheet with the new location information. This document does not require IRB approval. The study team will need to document in the study record when each research subject was given the new address information.

Frequently Asked Questions

1. Is there a new process we should follow?

Submit a protocol/application/document change amendment in iRIS to change the address in the consent/assent and, if applicable, update the sites listed in the IRB application.

2. Is there a “grace period” for enrolling subjects if the consent/assent address changes have not been approved?

You can use the currently approved consent/assent but if it has the wrong address, please inform the subject of the new address and document this conversation in the study record.

3. Can the old address be crossed out and the new address be handwritten in until the document is approved? Do I then need to complete a note to file?

Never alter a consent form without first submitting the changes to the IRB for approval. Give the subjects the new address in the same manner you are notifying all patients. Document this conversation in the study record.

4. How do we handle the study documents for those studies that are closed to enrollment, but not closed with the IRB?

Studies closed to enrollment do not need to be modified. However, if the study opens back up for enrollment, all documents will need to be amended to reflect the current information.

5. Other than the consent/assent address changes, are there other IRB documents that need to be updated?

Subject fliers and information cards as well as the study sites section in the application need to reflect the current information.

For any additional questions or concerns, please contact the HSPPO at hspofc@louisville.edu or 502.852.5188.