Title	Consent Documentation
Contact	researchcompliance@luriechildrens.org
Scope	This guidance applies to the Investigators and designated research personnel responsible for documenting the informed consent process and maintaining informed consent documents. It is essential that the steps of obtaining informed consent are properly documented in the participant study file and/or medical record, when appropriate.
Definitions	**Please see Glossary of Terms**

Procedure	• The documentation of the informed consent process is in addition to obtaining signatures on the informed consent form (ICF).
	  ○ The documentation of the consent process may be executed using a smart phrase in Epic (electronic medical record (EMR)), a separate checklist, Notes To File (NTF) or a memo in the participant file.
	  ○ This documentation should align with the IRB-approved consent process.
	• The Principal Investigator (PI) or designated research personnel who obtains the informed consent is the responsible party for documenting the process. Complete documentation includes the elements outlined in the IRB's Policies and Procedures Manual.
	• Documentation of the consent process can be maintained in the following locations:
	  ○ Participant file (paper or electronic)
	  ○ EMR
	• When re-consent is required: each ICF version that is signed should be followed by the respective ICF documentation in reverse chronological order with the current approved version first (on top).
	• All original signed consent forms must be retained in the participant file.
	• Errors and discrepancies such as documentation not completed within a timely manner of obtaining informed consent, should be explained with NTF (see NTF guidance document).

References	• Lurie Children's IRB Policies and Procedures Manual Section 11: Informed Consent Process • CRPedia Documentation Checklist Template • PAM Documentation of Consent Checklist
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