Title	Source Documentation
Contact	researchcompliance@luriechildrens.org
Scope	This guidance applies to the Investigators and designated research personnel who are responsible for maintaining source documentation and trial records. Source documentation serves to confirm participant eligibility, validate the integrity of trial data, and confirm observations that are recorded.
Definitions	**Please see Glossary of Terms**
Policy	This guidance is in compliance with Code of Federal Regulations (CFR), International Council for Harmonization (ICH) Good Clinical Practice (GCP) (E6), and other guidelines that apply to the involvement of human research participants in clinical research.
Procedure	1. Designated research personnel will prepare source documentation of every visit, conversation, and procedure/assessment associated with a research study. 2. Research staff will collate and/or collect source data for every data point on the appropriate document or case report form (CRF) as applicable. If these data are printed from the electronic medical record (EMR) the print date may not be reflective of the date reviewed by the Investigator or designee. 3. Research staff will ensure that all data is verifiable, and all documentation has an audit trail. 4. Qualified research personnel will apply the **ALCOAC** standard to achieve data quality: a. **A**ttributable: It should be obvious who wrote or did what. b. **L**egible: Record can be easily read. Changes should be properly documented. Never use pencils to record source documents, use ink for hand written entries. Avoid abbreviations. c. **C**ontemporaneous: The information should be current and documented in the correct time frame. d. **O**riginal: Original document or exact representation of original/certified copy. e. **A**ccurate: Data should not conflict. Content should precisely reflect the event being recorded and should represent the facts. f. **C**omplete: The documentation includes all of the necessary information. 5. Any changes to source documents should be traceable, should not obscure the original entry, and should be explained if necessary (e.g., via an audit trail). If source documentation is incorrect, incomplete, or otherwise deficient, research personnel may correct and/or complete by making an

	additional entry or addendum to the source documentation. The later entry must be signed/initialed and dated in present time by person making the entry. Errors in the EMR may need to be amended by the original note author. They would then amend their clinical note and an audit trail would be created within the EMR for the change. 6. Research personnel must NOT modify source documentation or regulatory documents in research records if they were not present or do not have another source document or record to reconcile. For example: If a coordinator did not sign the monitoring visit log and is no longer with the institution, the current coordinator should not affix either their own- name or the previous coordinator's name. Instead create a note-to-file explaining the circumstances and direct to supporting evidence. 7. If it is noted in the research record that data are missing and then obtained/found later, study personnel will incorporate the documents into the research record per the ALCOAC standard. 8. Study staff will follow any source documentation procedures outlined in the protocol or study manual. Study staff may utilize source documentation from the local EMR or that provided by the sponsor, institution, and any hard copies of subject questionnaires or CRFs. 9. The Investigator or designee must retain source documents for the required period outlined in the applicable regulations, institutional policies, and/or study contract. For example, the FDA requires maintenance of records for a period of two (2) years following the date a marketing application is approved for the drug for the indication for which it is being investigated.
References	• Lurie Children's IRB Policy and Procedures Manual Section 5: Principal Investigator Responsibilities Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice E6(R2) • FDA Guidance: Data Integrity and Compliance with CGMP
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