Title	Research Record Retention and Off-Site Storage
Contact	researchcompliance@luriechildrens.org
Scope	This guidance applies to the Investigators and designated research personnel responsible for maintaining and storing research files for current and closed studies.
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 guidelines that apply to the involvement of human research participants.
Procedure	• Research record retention can occur on-site or by utilizing one of the Lurie Children's approved vendors to store records (including research records) that can no longer be accommodated on-site. a. Principal Investigators (PIs) and designated personnel are to refer to the Clinical Trial Agreement (if applicable) for any specific storage guidelines. b. For any further questions, please contact the Office of Sponsored Programs (OSP) and/or the Office of Research Integrity and Compliance (ORIC). • Off-site storage is available for a fee and therefore Divisional and/or Departmental approval must be obtained prior to sending the records off-site. • The Division Administrator may provide the name and contact info for the preferred vendor and any applicable procedures for that specific division or department. • The PI and/or designated study personnel in the division will inform sponsors (when applicable) prior to sending any study records off-site: a. Via email (if the study is active or is still undergoing data analysis) b. During a study monitoring visit (if the study is active and monitoring is still taking place) i. If, after this notification, a sponsor requests review of records that are in off-site storage, the sponsor should notify the designated personnel at least two weeks prior to their site visit. • The PI and/or designated personnel will maintain detailed records of all study files stored off-site. Off-site research records must be able to be correctly located and subsequently recalled with the appropriate barcode ID at any time. A template is provided on CRPedia. a. Study records are to be packed in the boxes provided by the vendor. Each box must have a vendor-specific storage barcode and label. Each box, barcode, and the content(s) of the box will be recorded on the log. • All study records, either on- or off-site, must be retained according to Lurie Children's Record Retention and Disposal policies reference below. • After the retention period is complete, destruction of records should be

	determined by the Division Administrator and PI.
References	• Lurie Children's IRB Policy and Procedures Manual Section 3: IRB Record Retention • Lurie Children's Policy on Record Retention
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