Title	Notes to File (NTF)
Contact	researchcompliance@luriechildrens.org
Scope	This guidance applies to the Investigators and designated research personnel who are responsible for NTFs.
Definitions	**Please see Glossary of Terms**
Procedure	Notes to File may be used in the following instances: • To document the reason for a missing, delayed/late, or incorrect document in the regulatory binder and/or study files • To explain protocol deviations as requested* • To explain any Lurie Children's site-specific practices • To document and address an issue and the corrective action plan • Other(s) as applicable Use discretion when writing or being requested to generate NTF. Many policies and procedures can be used in lieu of adding a NTF. Providers can also provide annotated amendments to their notes in Epic to clarify clinical questions. *It is recommended that any protocol deviations explained by NTF should also be listed on the study team's deviation log. Notes to File should: • Be created on a case-by-case basis • Include the participant ID(s) and protocol it references • Be signed and dated by the individual (author) who is writing it • Be signed and dated by the Principal Investigator (PI) as applicable • Be completed on institutional letterhead (that means you should see the hand logo) • Be legible, if handwritten • Explain clearly and *specifically* the reason for the error/omission/discrepancy or process/policy it aims to address • Should include any corrective action or follow-up action when applicable • Be filed with the document, participant file, or behind the study binder tab to which it applies. • Be created on a timely basis upon knowledge of the error and/or issue.
References	NIH Guidelines for Writing Notes to the Study File
Attachments	CRPedia Note to File Template
Author(s)	Lurie Children's CRP Steering Committee
Approval	Stanley Manne Children's Research Institute – 6/16/2020