

Table of Contents

- Study Regulatory Binder: Instructions
- Study Contacts and Children's Hospital Resources

Subject Screening and Enrollment

MOO/SOP: Manual of Operations or Standard Operating Procedures

Study Protocol

Informed Consent and Assent Forms

Memos-to-File

Adverse Events and Unanticipated Problems

Protocol Deviations and Exceptions

Data and Safety Monitoring

Recruitment Materials

Case Report Forms (CRFs), Study & Subject Documents

Study Staff Logs and CVs

CCI/IRB Documentation

Scientific Review

FDA Forms 1571/1572, or IDE: Statement of Investigator Commitment

Regulatory Documentation: Sponsor-Investigator IND/IDE Holder

Regulatory Documentation: Investigator

Monitoring Log/Reports

Drug/Device Accountability Log

Laboratory Documentation

Investigational Brochure/Report of Prior Investigations or Package Insert/Device Manual

