Boston Children's Hospital
Until every child is well

Clinical Trial Study Documents

The following is a list of study documents, logs and information that should be available during the conduct of the protocol. Please note that this list is not inclusive but represents standard documents required of studies falling under FDA authority; if other study documents are deemed necessary prior to or during the study, the sponsor should add them accordingly.

IRB Documents

☐ IRB Approved Protocol - all versions: current and expired	
☐ IRB Approved Consent/Assent Forms - all versions: current and expired for each form (e.g. consent, assent, case/control)	
☐ IRB approval letters - for initial, continuing review(s) and amendments	
☐ IRB review documentation - for each review: submission, determination letters (e.g. conditional approval, deferral), pertinent correspondence and corresponding approval letters (above)	
☐ Recruitment Materials (all versions)	

☐ SAE, Unanticipated Problems and Protocol Deviation Reports - submitted report, pertinent correspondence and IRB/sponsor acknowledgement	
☐ DSMB Reports	

Study Documents

☐ Manual of Operations (MOO) - all versions: current and expired	
☐ Case Report Forms (CRFs) *and* Study Forms – all versions	

☐ Study Staff: Delegation of Roles and Responsibilities	
☐ CV/Licenses and training documentation for all staff as applicable	
☐ Financial Disclosure and Conflict of Interest Forms – as applicable	

☐ IRB Membership Roster	
☐ Drug/Device Accountability Log	
☐ Copy of Drug Label	
☐ Investigator's Brochure (IB) or Drug Insert *for drug studies* Reports of Prior Investigations (ROPI) *for device studies*	
☐ Normal Values/Ranges for all Labs used for study results	
☐ Accreditation, CLIA Certification & CV for Lab Director for all Labs	
☐ Monitoring Log and copies visit reports or letters	

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Sponsor, Contracts and Grants

☐ Investigator Agreements (with Sponsor), if applicable	
☐ Financial Agreements (budgets, contracts) if applicable	
☐ Grants	

FDA Submission, Reports and Correspondence

☐ FDA Form 1572: signed, all versions	
☐ FDA Form 1571 (IND Application): signed, all versions	
☐ FDA acknowledgement letters or request for changes	
☐ FDA annual reports	
☐ Serious or unexpected event reports, as applicable	
☐ Pertinent correspondence with FDA	

Subject Case History and Records

☐ Subject Screening/Enrollment Logs	
☐ Signed consent/assent forms	
☐ Completed CRFs	
☐ Source Documents (corresponding with CRFs)	
☐ Study visit notes/checklists	
☐ Memo-to-files (note-to-files)	
☐ SAE/unanticipated problems reports and follow-up	
☐ Pertinent correspondence with subject/family	

Other documents/records

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