Clinical Trials Quality Review Tool

Children's Healthcare of Atlanta

Study Title:	
IRB Number:	
Principal Investigator:	
Sponsor:	
Reviewer(s):	
Date(s) of Review:	

Instructions

This form is designed for use by investigators and research staff to assess compliance with federal regulations, federal guidance and CHOA Policies. For noncompliant items in this report, include comments to explain the deficiency. Deficiencies should be promptly corrected. Consider the Sponsor's and IRB's reporting requirements for protocol deviations and/or noncompliance and submit reports accordingly. Address significant or repeated issues of noncompliance with a written corrective and preventive action (CAPA) plan.

For Data and Safety Monitoring Plans (DSMPs) that require Self-Monitoring ***by the Study Team,*** please complete this review tool and email to the following email address: researchmonitoring@choa.org
Study Teams should complete Self-Monitoring tool according to the specifications in the IRB approved protocol.

For questions, please contact the QA/QI Team at the following email address**:** researchqaqi@choa.org

Regulatory Essentials				
Note: if any of the below items are maintained in a location other than the regulatory binder please confirm the location of the documentation with a Note to File in the regulatory binder.				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Is Investigational New Drug (IND) or Investigational Device Exemption (IDE) document present?	
All items below are pertaining to Investigators on the 1572 or Investigators Agreement only.				
☐	☐	☐	Are all signed versions of the Form FDA 1572 (drug or biologics studies) or Investigator Agreement (device studies) signed by the site PI?	
☐	☐	☐	Did all investigators have active CITI certifications through the study? *(Good Clinical Practice, Socio-Behavioral, Biomedical, etc.)*	
☐	☐	☐	Are all the appropriate investigators listed on the 1572/Investigators Agreement?	
☐	☐	☐	Are there current CVs (within the last 2 years) for all investigators listed on the 1572/Investigators Agreement?	
☐	☐	☐	Are there current licensures (medical license, APP, RN, etc.) for all investigators listed on the 1572/Investigators Agreement?	
☐	☐	☐	Are Financial Disclosure Forms (FDF) or FDA Form3455 completed by each investigator on the 1572/Investigator Agreement?	
☐	☐	☐	Have all investigators expressed any conflicts of interest pertaining to study?	

Other Regulatory Essential Items				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Are all protocol versions present?	
☐	☐	☐	Are all signed protocol signature pages present, if applicable?	
☐	☐	☐	Are all unsigned IRB approved copies of the Consent/Assent versions present?	
☐	☐	☐	Are all Package Inserts, or Device Manuals present?	
☐	☐	☐	Are all Investigator Brochures versions present?	
☐	☐	☐	Are all signed Investigator Brochure signature pages present, if applicable?	
☐	☐	☐	Is the study registered with clinicaltrials.gov, if applicable?	
☐	☐	☐	Is there a screening and enrollment log?	
☐	☐	☐	Are there blank case report forms (CRFs) included as part of the essential documentation?	

☐	☐	☐	Are all IRB approved study advertisements present?	
☐	☐	☐	Are the essential documents neatly organized and easy to locate?	

IRB				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Is the IRB Federal Assurance Number documentation present?	
☐	☐	☐	Are all IRB membership lists present?	
☐	☐	☐	Does the study currently have IRB approval?	
☐	☐	☐	Did the study have IRB approval throughout? *If no, were any activities that occurred during lapse reported to the IRB?*	
☐	☐	☐	Are all IRB approval letters (initial approval, amendments, continuing review, and reportable events) present with the essential documents?	
☐	☐	☐	Did the IRB approve all versions of the protocol, informed consent, assent, and investigator's brochures (IBs)?	
☐	☐	☐	Is the Children's Addendum for Multi-Site studies present, if applicable?	
☐	☐	☐	Were the reportable events that were reported to the IRB reported appropriately in regard to event type and time of report?	
☐	☐	☐	If subjects withdrew from study, were withdrawals reported to the IRB at continuing review?	
☐	☐	☐	Is the IRB approved DSMP being followed?	
☐	☐	☐	Is the IRB approved protection plan being followed, to include use of encrypted devices?	
☐	☐	☐	Is there documentation that partial HIPAA waiver was granted?	
☐	☐	☐	Were all publications submitted at Continuing Review and/or Close out?	

Study Staff Items				
Note: if any of the below items are maintained in a location other than the regulatory binder please confirm the location of the documentation with a Note to File in the regulatory binder.				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Are there current CVs (within last 2 years) covering dates of the research for all study staff on the Delegation of Authority Log, as applicable?	
☐	☐	☐	Are there current licenses for all study staff on the Delegation of Authority Log, as applicable? (example:	

			Research Pharmacist, Research Nurse)?	
☐	☐	☐	Did all study staff have active CITI certification throughout the study? *(Good Clinical Practice, Socio-Behavioral, Biomedical, etc.)*	
☐	☐	☐	Is the study team contact list/information available?	
☐	☐	☐	Is the Delegation of Authority Log (DOA) complete and accurate?	
☐	☐	☐	Do all study staff have IRB approval?	
☐	☐	☐	Have any study staff expressed any conflicts of interest pertaining to study?	
☐	☐	☐	Is there documentation of study-specific training for all study staff?	
☐	☐	☐	Were study staff trained to all versions of protocols, manuals, or IBs?	
☐	☐	☐	Is there documentation of ARUP or IATA training for all study staff who package and ship biological materials?	
☐	☐	☐	Do any study staff members fall within the category of CHOA Contingent Researchers"? *Contingent Researchers*	
☐	☐	☐	If your study has CHOA Contingent Researchers have, they completed CHOA non-Employee Research Onboarding? (reach out to ResearchEducation@choa.org for more information)	

Lab Items

Note: if any of the below items are maintained in a location other than the regulatory binder please confirm the location of the documentation with a Note to File in the regulatory binder.

Local Lab ☐ *Not Applicable*

Complete?			Item	Comments
Yes	No	NA		
☐	☐	☐	Is there documentation of Clinical Laboratory Improvement Amendments (CLIA) certification?	
☐	☐	☐	Is there documentation of College of American Pathologists (CAP) certification?	
☐	☐	☐	Is there documentation of validation or calibration test methods? (*Reach out to Research Laboratory for these documents).*	
☐	☐	☐	Are the normal range values of labs present? *(Reach out to Research Laboratory for these documents).*	

Central Lab ☐ *Not Applicable*

Complete?			Item	Comments
Yes	No	NA		

☐	☐	☐	Is there documentation of Clinical Laboratory Improvement Amendments (CLIA) certification?	
☐	☐	☐	Is there documentation of College of American Pathologists (CAP) certification?	
☐	☐	☐	Is there documentation of validation or calibration test methods? *(Reach out to Sponsor or Central Laboratory for these documents).*	
☐	☐	☐	Are the normal range values of labs present? *(Reach out to Sponsor or Central Laboratory for these documents).*	

Reportable Items

Adverse Events (AEs) ☐ *Not Applicable*

Complete?			Item	Comments
Yes	No	NA		
☐	☐	☐	Was there documentation of review, grade, and attribution of external adverse events by the PI or other qualified study team member?	
☐	☐	☐	Were adverse events appropriately reported to the sponsor?	
☐	☐	☐	Were adverse events appropriately reported to the IRB, if applicable?	
☐	☐	☐	Were serious adverse events (SAEs) appropriately reported to the IRB?	

Protocol Deviations (PDs)

Complete?			Item	Comments
Yes	No	NA		
☐	☐	☐	Were there changes to the research protocol without IRB approval?	
☐	☐	☐	Were protocol deviations reported appropriately to the sponsor in regard to type and time of report?	
☐	☐	☐	Were protocol deviations reported appropriately to the IRB in regard to type and time of report?	

Investigational Product Accountability

Investigational Therapeutic (drug, biologic, etc.) ☐ *Not Applicable*

Note: if any of the below items are maintained in a location other than the regulatory binder please confirm the location of the documentation with a Note to File in the regulatory binder.

Complete?			Item	Comments
Yes	No	NA		
☐	☐	☐	Is the IRB approved plan for storage and dispensation of the IP being followed? *(Reach out to IDS Pharmacy for information if not stored in site regulatory binder)*	
☐	☐	☐	Are the instructions for handling/storage of the IP present and available? *(Reach out to IDS Pharmacy for information if not stored in site regulatory binder)*	

☐	☐	☐	Was the investigational product (IP) stored in accordance with the instructions? *(Reach out to IDS Pharmacy for information if not stored in site regulatory binder)*	
☐	☐	☐	Was the drug kept in the IDS Pharmacy?	
☐	☐	☐	If the drug was not kept in IDS Pharmacy, did the IDs grant a waiver?	
☐	☐	☐	Is there a record for investigational product dispensation? *(Reach out to IDS Pharmacy for information if not stored in site regulatory binder)*	
☐	☐	☐	Is there a record for investigational product return, including destruction? *(Reach out to IDS Pharmacy for information if not stored in site regulatory binder)*	
☐	☐	☐	Are IP drug package inserts present or available? *(Reach out to IDS Pharmacy for information if not stored in site regulatory binder)*	

Investigational Medical Device Accountability ☐ *Not Applicable*

Complete?			Item	Comments
Yes	No	NA		
☐	☐	☐	Are the instructions for handling/storage of the Investigational device present and available?	
☐	☐	☐	Was the device stored in accordance with the instructions?	
☐	☐	☐	If a medical device study, was the device kept in the CVOR or OR storage?	
☐	☐	☐	Was the device kept in a secure place and labeled “investigational”?	
☐	☐	☐	Is there a record of device accountability present including receipt, implant in subject and shipment back to sponsor/supplier?	
☐	☐	☐	Is there a device manual present?	
☐	☐	☐	Are there any required training materials and/or training logs present for investigators and trained study staff?	

Monitoring and Data Safety and Monitoring Plan (DSMP)

Complete?			Item	Comments
Yes	No	NA		
☐	☐	☐	Was the monitoring frequency consistent with the DSMP as approved by the IRB?	
☐	☐	☐	Did the monitoring reports reveal any significant noncompliance issues?	
☐	☐	☐	Did the monitoring reports reveal any patterns of ongoing or unresolved noncompliance?	
☐	☐	☐	Did the sponsor take action in response to	

			noncompliance?	
☐	☐	☐	Were the DSMB reports submitted to the IRB appropriately?	

EPIC and CTMS

EPIC

Complete?			Item	Comments
Yes	No	NA		
☐	☐	☐	Have all subjects been assigned to research study in EPIC by selecting: ENROLLED?	
☐	☐	☐	Has the subject ID been entered into EPIC for subjects?	
☐	☐	☐	Have all subjects who have completed study been updated in EPIC to, COMPLETED?	
☐	☐	☐	If subjects were withdrawn or screen failures have, they been updated in EPIC to WITHDRAWN or INELIGIBLE?	
☐	☐	☐	Are subject visit encounters being linked to the research study in EPIC prior to study visit, if applicable?	

CTMS

Complete?			Item	Comments
Yes	No	NA		
☐	☐	☐	Have all subjects been tracked in CTMS for the research study?	

Feasibility/Intent to Submit/Department Approvals

Complete?			Item	Comments
Yes	No	NA		
☐	☐	☐	Is there a Children's Feasibility Approval for this study? *(note: some older studies may have a Departmental Approval Form aka DAF).*	
☐	☐	☐	Is there an Emory Intent to Submit Approval for this study?	
☐	☐	☐	Have all required ancillary departments to complete protocol been approved?	
☐	☐	☐	Is there a current Children's NOA for this study?	
☐	☐	☐	Is there a current Emory NOA for this study?	

Sponsor-Investigator or Investigator-Initiated study ☐ Not Applicable

FDA Documentation				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Is the original IND (1571)/IDE application present?	
☐	☐	☐	Is the FDA letter of no objection present?	
☐	☐	☐	Are amendments to the 1571/IDE application present?	
☐	☐	☐	Are the annual reports present?	

Adverse Events				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Is there documentation that the sponsor-investigator notified the FDA by phone or fax of any unexpected fatal or life-threatening event associated with the drug/device within 7 calendar days after initial receipt of the information?	
☐	☐	☐	If the sponsor-investigator determined that there were unreasonable and significant risk to subjects from the investigational product, is there documentation that the sponsor-investigator discontinued the study and notified the IRB within 5 days working days of making the determination?	
☐	☐	☐	Is there documentation that the sponsor-investigator notified the FDA within 15 calendar days via IND/IDE safety reports of adverse events related to the drug/device that are both serious and unexpected, and/or findings in laboratory animals that suggest a significant risk for humans?	

Monitoring				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Is there a monitoring plan to ensure that the investigation is being conducted in compliance?	
☐	☐	☐	Is the plan being followed?	
☐	☐	☐	If the sponsor-investigator has transferred monitoring responsibilities to a contract research organization, is the transfer described in detail in writing?	

Investigational Product (Drug, device, biologic, etc.)				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Are there written procedures that include instructions for handling and storage of investigational product(s)	
☐	☐	☐	Is there documentation that the sponsor-investigator has maintained adequate records showing the receipt,	

			shipment, or other dispensation of the investigational product? (This information is maintained by the IDS if the drug is stored in IDS.)	

Multi-site Studies when Emory is the Coordinating Site ☐ Not Applicable

Essential Documentation				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Are the 1572s or Investigator Agreements from all sites present?	
☐	☐	☐	Are the CVs from all site(s) participants present?	
☐	☐	☐	Is there documentation that the sponsor-investigator supplied the investigator's brochure/device manual to all sites?	
☐	☐	☐	Is there documentation that the sponsor-investigator has obtained financial disclosure information and/or changes to financial information from all participating sites?	
☐	☐	☐	Is there documentation of review and evaluation of research data for safety and effectiveness as it is obtained by all participating sites?	
☐	☐	☐	If the sponsor-investigator determined that there were unreasonable and significant risk to subjects from the investigational product, is there documentation that the sponsor-investigator discontinued the study and notified all participating sites and all site IRBs within 5 days of making the determination?	
☐	☐	☐	Is there documentation that the sponsor-investigator notified all the participating sites within 15 calendar days via IND/IDE safety reports of adverse events related to the drug/device that are both serious and unexpected, and/or findings in laboratory animals that suggest a significant risk for humans?	
☐	☐	☐	Is there a monitoring plan to ensure that the investigation is being conducted in compliance across all participating sites?	
☐	☐	☐	Is the monitoring plan being followed?	

Investigational Product/ Medical Device ☐ *Not Applicable*				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Are there written procedures that include instructions for handling and storage of investigational product (IP)/investigational medical device?	
☐	☐	☐	Is there documentation that the IP/investigational medical device was shipped only to investigators conducting the study?	
☐	☐	☐	Is there documentation that the sponsor-investigator has maintained adequate records showing the receipt, shipment, or other dispensation of the investigational product at all participating sites?	
☐	☐	☐	Was the drug dispensed according to the protocol?	

☐	☐	☐	Was the device used or implanted according to the protocol?	
☐	☐	☐	Were drug diaries completed for the study drug?	
☐	☐	☐	Is there documentation of the return or destruction of all unused investigation product, medical devices, patient handouts and/or advertisements?	

Subject Review

Choose the number of at least 10% of the total number of subjects enrolled to date or 2 charts, whichever is greater. Randomly pull that number of subject charts for review. Ensure that there is adequate source documentation for all research data. Copy the Subject Review questions below and paste it for as many subjects as you will audit.

Subject XX-XXX: _____

Informed Consent				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Did the subject give written consent and/or reconsent by personally signing and dating the ICF and/or assent?	
☐	☐	☐	Did the subject sign or initial optional research on the ICF and/or assent (e.g. biorepository, tissue bank, etc.)?	
☐	☐	☐	Did the subject sign and date the ICF and/or the assent prior to research procedures/interventions?	
☐	☐	☐	Did the subject sign and date the correct IRB-approved version of the ICF and/or assent?	
☐	☐	☐	Is the person obtaining consent approved as study staff by the IRB and delegated to obtain consent on the study delegation log?	
☐	☐	☐	Is there documentation of the consent process in EPIC, written NTF or other applicable databases?	
☐	☐	☐	Is there documentation that a copy of the consent/assent was given to the subject?	
☐	☐	☐	Did the subject give written HIPAA Authorization by singing and dating the HIPAA Authorization form *(this form may be combined with the consent document)?*	
☐	☐	☐	Was a copy of the Informed Consent/Assent sent to Medical Records for upload to EPIC?	
Eligibility				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Was the subject registered correctly in EPIC, CTMS and/or OnCore?	
☐	☐	☐	Is there source documentation to support that all eligibility criteria were met?	
☐	☐	☐	Is there documentation of eligibility verification by the PI or other qualified research team member?	
☐	☐	☐	Were all pre-enrollment activities completed per protocol?	
☐	☐	☐	Was the subject added to the enrollment log or subject ID log?	
☐	☐	☐	Was the medical history obtained and recorded as required by the protocol?	
Treatment/Intervention ☐ ***Not Applicable***				

Complete?			Item	Comments
Yes	No	NA		
☐	☐	☐	Did the subject take any protocol prohibited medication during the study?	
☐	☐	☐	Was the subject dosed/treated according to protocol?	
☐	☐	☐	Was the correct treatment schedule followed per protocol?	
☐	☐	☐	Was there adequate documentation of treatment, including pre-meds and others?	
☐	☐	☐	Was the dose/treatment adjusted for toxicities per the protocol and were the reasons provided?	

Adverse Events ☐ *Not Applicable*

Complete?			Item	Comments
Yes	No	NA		
☐	☐	☐	Was there documentation of prompt review of all adverse events by the PI or other qualified study staff member?	
☐	☐	☐	Was there documentation of type, grade, attribution, and dates/duration for all adverse events?	

Protocol Adherence

Complete?			Item	Comments
Yes	No	NA		
☐	☐	☐	Is there source documentation to support that all tests/procedures were implemented per the protocol?	
☐	☐	☐	Were the appropriate test/procedures documented as being reviewed by the PI or other qualified research team member?	
☐	☐	☐	If a procedure was missed, was the reasons appropriately documented?	
☐	☐	☐	Were the protocol deviations in the source documentation appropriately considered and recorded as protocol deviations?	
☐	☐	☐	Is there documentation to support that all required samples were obtained and stored appropriately?	
☐	☐	☐	Is the follow-up schedule for subjects being followed per protocol (are research visits conducted in window per protocol)?	

Data Management

Complete?			Item	Comments
Yes	No	NA		
☐	☐	☐	Is the data quality complete and appropriate?	
☐	☐	☐	Is the case/medical history maintained appropriately?	
☐	☐	☐	Is the research file organized?	
☐	☐	☐	If source data verification was performed, was the data accurately recorded on the case report forms and/or electronic data capture system?	

Investigational Therapeutic Accountability ☐ *Not Applicable*				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Was the drug ordered by a physician who is named on the 1572 and approved by the IRB?	
☐	☐	☐	Was the drug dispensed according to the protocol?	
☐	☐	☐	Were drug diaries completed for the study drug?	
☐	☐	☐	Was returned or destroyed study drug documented?	

Medical Device Accountability ☐ *Not Applicable*				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Was the device used or implanted according to the protocol?	
☐	☐	☐	Are there device package labels associated with subject in subject binder?	

CTMS and Invoiceable Items☐ *Not Applicable*				
Complete?			**Item**	**Comments**
Yes	No	NA		
☐	☐	☐	Is subject correctly entered in CTMS with appropriate calendar(s) to track visits?	
☐	☐	☐	Were subject research visits linked to encounter in EPIC?	
☐	☐	☐	Are OGA Invoices accurately reviewed and verified prior to sign-off by coordinator or other study staff member?	
☐	☐	☐	Are IDS Pharmacy invoices reviewed, verified and saved?	
☐	☐	☐	Are Laboratory invoices reviewed, verified and saved?	

Other comments (if applicable:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Signature:

Signature and date of the study staff member completing this form

Signature and date of the Investigator reviewing this form

Please send this report to Research QA/QI at **researchmonitoring@choa.org**
Date sent to Research QA/QI: _____