HRP-919 | 8/16/2024

FORM: QI Report

Study Title:	
CHLA IRB #:	
Principal Investigator:	
Study Coordinator:	
Review Date(s):	
QA Auditor:	

Comments:
This report was reviewed with the Principal Investigator **and/or** study coordinator at a post-review meeting. The following items will be revised based on the post-review responses during the meeting on **XX-XX-XXXX**: ***<put NA if not applicable>***

After receipt of the electronic copy of the final report, a point-by-point response is required in:
☐ 14 days ☐ 30 days ☐ 45 days ☐ 60 days

Executive Summary
The study entitled **< >** is **<**audited or reviewed**>** for compliance with AAHRPP accreditation standards, ICH E6 Good Clinical Practice (GCP) Guidance DHHS and FDA regulations, and Children's Hospital Los Angeles Human Subjects Protection Program policies and procedures.

Observations noted are detailed in section the **Quality Review Findings Details/Action Plan** section of this document.

Evidence of good practices include but are not limited to:
- ✓ *Procedures are conducted at protocol-defined intervals.*
- ✓ Abnormal lab results are reviewed in a timely manner.
- ✓ Regulatory and subject binders are available and in order.
- ✓ Records for drugs and device accountability are present.

Copies of the report were sent to the Human Subjects Protection Program (HSPP) Regulatory Affairs Manager and the Executive Director for notification. Findings that represent safety concerns to subjects must be communicated to the IRB by completing a Reportable Event application in iStar. The Principal Investigator is responsible for completing the Reportable Event application.

General Information
< > IRB (CEDED) originally approved the study on **< >**, CHLA IRB **acknowledged/approved** on **< >,** and **< >** subjects enrolled.

The study sponsor is **< >.** The study is funded by **< >.** The study has an IND. The IND # is **< >.** The sponsor/investigator holds the IND. There is a Data Safety Monitoring Board, which is scheduled to meet **< >.**

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Audit Scope and Approach
The audit included a review of the following:

- ✓ Eligibility
- ✓ Informed Consent/Assent
- ✓ Documentation
- ✓ Laboratory
- ✓ Regulatory Review
- ✓ Review of Investigational Products

This report contains findings in RED that should be addressed to comply with regulatory standards.

Element Summary

IRB Approval
IRB approval memo (initial) is on file.
IRB approval memo (amendment) is on file.
IRB approval memo (continuing review) is on file.

- **<describe any findings>**

IRB/Sponsor Correspondence
Sponsor correspondence is up to date ***(Recommended)***
IRB Membership Roser(s) on file.
IRB **Registration / Reliance Agreement** is on file.

- **<describe any findings>**

Eligibility (Inclusion/Exclusion)
Source documents for eligibility are on file. ***(Required)***
<insert number> subjects met eligibility criteria.

- **<describe any findings>**

Screening *(if applicable)*
The screening log is up to date ***(Recommended)***
Screen failures are documented.

- **<describe any findings>**

Recruitment
Recruitment materials are on file.
Recruitment materials are approved by the IRB.

- **<describe any findings>**

Enrollment
Enrollment logs exist, and documents enrolled participants ***(Recommended)***
The enrollment log is up to date.
Enrollment log matches the number of subjects recruited.
Enrollment numbers match the number cited in the continuing review.

- **<describe any findings>**

Informed Consent/Assent
All versions of blank IRB-approved informed consent forms are filed chronologically in the regulatory binder.
Informed consent history log is up to date ***(Required)***
The re-consenting plan was developed and is on file.
Current IRB-approved consent forms were used.
Notes to the informed consent process are used and filed in the participant research charts. ***(Required)***
Signatures and dates on consent forms are appropriate.

Assent is obtained (as required by the IRB)
Signatures and dates on assent forms are appropriate.
Subjects were re-consented using the appropriate form.

- **<describe any findings>**

Protocol Adherence and Safety Measures
All protocol versions and associated documents are on file.
All amendments and associated documents are on file.
Principal Investigator and sponsor agreements are on file.
Study visits and procedures are conducted at protocol-defined intervals.
Study procedures are performed by study personnel delegated to conduct these tasks.

- **<describe any findings>**

Randomization
Randomization schema is on file.
IVRS training is documented.
Decoding instructions are on file.

- **<describe any findings>**

Protocol Deviations
Protocol deviation log is up to date ***(Required)***
Applicable protocol deviations are filed with the IRB.

Remedial plans are proposed on the protocol deviation.
Corrective Actions Preventive Actions (CAPA) plans are developed when indicated.

- **<describe any findings>**

Serious Adverse Event
Serious adverse event log is up to date ***(Required)***
A serious adverse event reporting plan is on file.
Adverse events, serious adverse events, and unanticipated problems involving risks to subjects and or others have been reported immediately or during continuing review (per institutional policy)
Subject participation is discontinued if serious or life-threatening events are based on protocol-specific criteria (these are contained in the regulatory binder)

- **<describe any findings>**

Site Monitoring
Site monitoring report log is up to date ***(Required)***
Site monitor reports are on file.
Responses to the site monitor's requests are on file.
Site monitor issues/data clarification are acted upon.

- **<describe any findings>**

Case Report Form and Source Documentation
Study-specific source document templates are filed in the eRegulatory Binder and up to date ***(Recommended)***
Study files are organized, complete, legible, and recorded in black or blue ink.
Source documents are complete, signed, and dated appropriately for each visit.

Case report forms set is on file and utilized for each subject.
Case report forms are consistent with source documents.
Case report form completion rate is satisfactory for the forms reviewed.
Case report form entries are signed and dated as appropriate.

- **<describe any findings>**

Delegation of Authority
Delegation of authority log is available and up to date ***(Required)***
Delegation of authority log signatures and dates are in place.
Delegation of authority log is accurate.

- **<describe any findings>**

Curriculum Vitae *(Required)*
Study files contain up-to-date CVs of investigators and core study team members.
These forms are signed, dated, and no more than two years old.

- **<describe any findings>**

Evidence of Training
Training on the protocol is evident and documented (includes new study team members)
Minutes between the trainer and the study team are on file.
Training log is on file ***(Required)***
Training – site initiation visit log is on file.
Site initiation visit materials are on file.
Training – The investigator's meeting attendance is documented.
Training meeting minutes of the Principal Investigator and staff meeting attendance are filed.
Institutional CITI training is on file.

- **<describe any findings>**

Laboratory
Laboratory certifications, reference ranges, and licenses (if applicable) are in the regulatory binder.
Lab Director's Curriculum Vitae is on file.
Abnormal lab results are reviewed in a timely manner and documented as clinically or not clinically significant by the Principal Investigator.

- **<describe any findings>**

Food and Drug Administration Forms and Contracts
Food and Drug Administration form 1571 is on file.
Food and Drug Administration form 1572 is on file.
Financial disclosure form 3455 is on file.
Contracts with the sponsor or NIH are on file.
Budget information is on file.

- **<describe any findings>**

Data Safety Monitoring Board
Data Safety Monitoring Board (DSMB) plan is on file.
Data Safety Monitoring Board (DSMB) reports are on file.
Data Safety Monitoring Board (DSMB) reports are filed with the IRB on time.
Data Safety Monitoring Board (DSMB) meetings have occurred as scheduled.

- **<describe any findings>**

Investigator Brochure
Study files contain all versions of the Investigator Brochure
The Investigator Brochure distribution log is on file. ***(Recommended)***

- **<describe any findings>**

Test Article/Investigational Drug/Device
Shipment log is up to date ***(Recommended)***
Drug/device accountability log is up to date ***(Required)***
The investigational drug or device is properly stored per CHLA HSPP policy and the iStar application.
Inventory and product accountability forms are complete and accurate.
A copy of all documentation related to "unanticipated problems involving risks to subjects and/or others," serious adverse events, and unexpected drug reactions is on file.

- **<describe any findings>**

Quality Review Findings Details/Action Plan

Eligibility:

Observation:
Recommendations:
Informed Consent/Assent:

Observation:
Recommendations:
Documentation:

Observation:
Recommendations:

Laboratory:

Observation:
Recommendations:

Regulatory Review:

Observation:
Recommendations:
Review of Investigational Products:

Observation:
Recommendations:

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Additional Study Team Training Recommendations:

- Clinical Research Coordinator Basic CITI Course Link
- **Ceded IRB 101** – Intro to Ceded/Reliance IRB + Office Hours /email regulatoryaffairs@chla.usc.edu to schedule.
- Human Subjects Protection Program (HSPP) and Institutional Review Board (IRB) ***Please Note:*** I recommend becoming familiar with Reliance on an External IRB for Review and Oversight section—scroll 3/4 down the homepage.
- CHLA HSPP Education and Training Sessions
- Become familiar with the attached Instructions for **Reliance on Another IRB** for Review and Oversight.
- **Regulatory & eRegulatory** (how to maintain and what is required) Training/email regulatoryaffairs@chla.usc.edu to schedule.
- Informed Consent Training iLearn Link
- Intro to Clinical Trials: Phases, Protocol, IND's, CRO's, and Sponsors iLearn Link
- Introduction to Good Documentation Practices (GDP) and Data Management iLearn Link
- Introduction to Human Subjects Research Ethics & IRB/iStar iLearn Link
- Introduction to KIDS for Research Coordinators iLearn Link
- Introduction to AEs/SAEs & Prompt Reporting iLearn Link
- Do you need a CHLA **IRB Member Roster** List for your regulatory binder? Contact the HSPP @ hspp@chla.usc.edu
- Do you need help with **Clinicaltrials.gov**? Contact Nathan Kamel @ clinicaltrials.govhelp@chla.usc.edu
- Essential Documents for the Conduct of a Clinical Trial ICH-GCP Link
- **ICH-Good Clinical Practice E6(R3) Link**

If you have questions or need further clarification, please contact me via email, Teams, or Ext 16302.

Warm Regards,

Andrea Smith, CCRP
Quality Assurance Program Manager
Human Subject Protection Program

Signature:		Date:	

[i] This document satisfies AAHRPP elements I.5.A, I.5.B, I-9.