CONFIDENTIAL

Study Audit Final Report

Principal Investigator		Department/Division:	
Protocol Number		Source of Funding:	
Protocol Title			
Type of Selection	☒ Randomized Selection ☐ PI Requested	Prepared by:	
Date of Review		Questions? Contact:	X55308

■ It is the responsibility of the Principal Investigator:

1. To thoroughly review, assess and respond to the findings in this report
2. To share and disperse copies of the report with appropriate research staff
3. To address all *Required Corrective Actions* and consider all *Recommended Actions*
4. Complete, sign and return the attached PI Response Form by email scanned attachment within 1 month of receipt to eunice.newbert@chidlrens.harvard.edu (Eunice Newbert):

■ Once the EQuIP office determines all required and recommended actions have been adequately addressed, the review will be formally closed.

Please note that this report is CONFIDENTIAL. The details specific to this report will not be shared with the IRB or other groups unless otherwise noted in this report. In such events, the PI will be notified before any information is shared. A copy will be filed in the EQuIP Office and will be available only to the PI, and the EQuIP staff.

I. Study Review Summary *overview of areas reviewed*

Areas Reviewed *Follow-up Action:*	**Required**	**Recommended**	**None**
IRB and Other Regulatory Reviews	☐	☐	☐
Protocol Records: Documentation & Organization	☐	☐	☐
Protocol Adherence and Conduct	☐	☐	☐
Protocol Deviation/Exceptions: Documentation & Reporting	☐	☐	☐
Unanticipated/Adverse Events: Documentation & Reporting	☐	☐	☐
Informed Consent/Assent: Process & Documentation	☐	☐	☐
Subject Records: Eligibility Criteria & Documentation	☒	☐	☐
Research Staff, Training & Education	☐	☐	☐

II. Notable Best Practices *overview of study strengths*

III. Identifying and Reporting Protocol Deviations and Unanticipated Problems

For each observation described in the following sections, please review the BCH/IRB Policy for 6.2 Unanticipated Problems Involving Risks to Research Subjects and Others Including Adverse Events to determine what should be reported to IRB and how.

A deviation is considered an unintentional event that departs from the approved protocol and identified retrospectively. The PI should promptly review each deviation and assess whether the impact on the study is considered *Minor* or *Significant*. It is up to the PI to determine a method of on-going review and documentation (e.g. log, memo-to-file), as long as all events are documented and reported as required.

- Minor Deviations: document all minor deviations/unanticipated problems in the study records using a consistent method, and submit a summary of all minor events at time of next continuing review.

  Note: if a corrected data point/value is made directly on the form, please ensure that the corrected date/value is not obscured (e.g. whited-out). The incorrect value should be crossed-out with a single line, the correct value added next to it and an explanation if the correction is not obvious. The person who makes the noted corrections should initial and date correction (date correction was made).

- Significant Deviations: once an event is determined to be Significant, submit to IRB immediately using the CHeRP Reportable Events Form within 72 hours.

Part A. Required Corrective Actions

A1. Category/Area	
Observation	
Required Action	1.
Reason	

A2. Category/Area	
Observation	
Required Action	
Reason	

A3. Category/Area	
Observation	
Required Action	

Part B. Recommended Actions

B1. Category/Area	
Observation	
Recommended Action	
Reason	

Required Corrective Actions and Recommendations

1. Category/Area	
Observation	
Required Action	
Recommended Action	
Reason	Reference IRB Guidance:

Just to Note

Revised IRB Guidelines & Policies	Many of the IRB Guidelines and Policies have been recently updated. Research team members can access all of the updated policies on the IRB Guideline and Policy section to familiarize themselves with the updated policies and stay informed about any changes that may affect current or planned research. 📖 Reference IRB Guidelines and Policies Page
~~**Important Change to Eligibility of Who can be a PI on an IRB Protocol**~~	~~Effective June 29, 2015, the eligibility criteria for who can serve as a Principal Investigator (PI) for non-exempt, human subject research protocols submitted to the IRB will change. The new policy seeks to implement a mechanism of accountability and continuity for human subject protections and is not intended to restrict academic productivity or leadership. Trainees may no longer serve as a PI of a protocol submitted to the IRB. Individuals who do not meet the criteria to be a PI may still participate as a Co-Investigator and perform leadership roles in the conduct of the research. Please link to the attached special communication for further information about this change.~~ ~~📖 Reference **Please click here for more information.**~~
IRB Reliance Agreement Resources	The IRB now has a dedicated resource in the form of an IRB specialist focusing on protocols with multiple institutions in which more than one IRB has jurisdiction. This includes managing reliance agreements (also known as cede requests) among IRBs for shared protocols. Daniel Alderson can be reached at daniel.alderson@childrens.harvard.edu or (617) 919-1918.
Non-English Speaking Subjects **Need to update with iPad**	Before enrolling any non-English speakers, first review the IRB guidance for documenting the involvement of a translator/interpreter in the consent process: 📖 Reference IRB Guidance Informed Consent with Non-English Speakers 📖 Reference IRB September 2014 Special Newsletter
Certificates of Confidentiality (CoC) NIH Policy	The NIH has changed its policy for issuing Certificates of Confidentiality for NIH-funded and conducted research. This updated policy applies to research started on or after 12/13/2016. 📖 Reference Notice of Changes to NIH Policy for Issuing CoC
Storing Informed Consent and Assent Forms in Medical Records	For most studies the signed consent forms are required to be stored in the subject's electronic medical records. 📖 Reference IRB 2016 June Newsletter (page 3) **[Attach FAQs on how to store in MR]**