✓ EQuIP at Children's Hospital Boston

Subject Audit Checklist

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Subject ID		Subject DOB	
Date Consent Signed		Date Enrolled	
Valid Consent Version	Activation Date:	Expiration Date:	
Version Signed	Activation Date:	Expiration Date:	

	YES	NO
Is the consent process documented in study files (source documentation)?		
Was an invalid consent form signed?		
If YES, were there any approved changes in the valid consent? could any of these changes affect the subject's decision to participate?		
Ly If VEO. DI much submit as a Cimplificant Deviation to COL/IDD		

- → If YES, PI must submit as a Significant Deviation to CCI/IRB
- → If NO, PI must submit as a Minor Deviation to CCI/IRB at next continuing review

Check the required signatures below, and then complete the appropriate information:

Subject Consent	Date signed:	
Subject Assent •If req'd, but not obtained, reason?	Date signed: Reason:	
Parent/Guardian	Date signed:	Relationship:
Parent/Guardian	Date signed:	Relationship:
PI/PI Associate	Date signed:	
Witness	Date signed:	

	YES NO
Were all required signatures obtained?	
Did all required signors correctly date their own signature?	
If NO, explain below:	

	YES	NO
Are all adverse events correctly documented and reported w/adequate follow-up?		
Are all deviations/exceptions correctly documented and reported w/adequate follow-up?		
If NO, explain below:		

Subject Eligibility: Inclusion/Exclusion Criteria

Inclusion Criteria: does subject meet the following criteria:

g	YES	NO
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•		
•		
•		
•		
•		
•		
•		
•		
If NO, explain below:		

Exclusion Criteria: does subject meet the following criteria:

	YES NO
•	
•	
•	
-	
•	
•	
If NO explain below:	

If NO, explain below:

Study Visits and Procedures

Visit/Procedure	Date completed	If not done, explain

	YES	NO
Were all missed/incomplete visits/procedures adequately documented and reported?		
Is there adequate source documentation available for each visit and procedure?		
If NO, explain below:		

General Notes and Observations