This protocol was reviewed in compliance with the 2018 Requirements in the Code of Federal Regulation at 45 CFR 46.		
Approval Period:		
Review Type:	Expedited Review	*45 CFR 46.110 – Category 5*
Risk/Benefit:	The study represent no more than minimal risk to subjects.	*45 CFR 46.102(j)*
Requirements of Informed Consent:	Informed Consent – **REQUIRED** – For Aim 2, consent will be discussed with parents of eligible subjects over the phone or in person. A translator and Short Forms will be used as necessary for non-English speaking parents.	*45 CFR 46.116(a-c)*
	Documentation of Informed Consent – **REQUIRED** – Signatures will be obtained electronically.	*45 CFR 46.117(a and b)*
Requirement of Permission by Parent(s)/ Guardian(s)	Permission by Parent(s)/Guardian(s) – **REQUIRED** – For Aim 2, consent will be discussed with parents of eligible subjects over the phone or in person	*45 CFR 46.404*
	Documentation of Permission by Parent(s)/Guardian(s) – **REQUIRED** – Signatures will be obtained electronically.	*45 CFR 46.408(d)*
	The Permission of one parent is sufficient.	*45 CFR 46.408(b)*
Assent by Children	Assent by Children – **WAIVED** – Children ages one month to four years are the eligible subjects.	*45 CFR 46.408(a)*
HIPAA Authorization:	**REQUIRED**: • To use subject identifiers (provided by CHCO) to identify newborn screening laboratory data • To disclose newborn screening laboratory data with subject identifiers back to CHCO for analysis	*45 CFR 164.512(i)(1)(A)*
Inclusion of Vulnerable Populations:	Children - **APPROVED**	*45 CFR 46.404*
	Pregnant women – **NOT APPLICABLE**	
	Prisoners – **NOT APPLICABLE**	