Reviewer Form –Initial Application

CHEO Study#

Summary: (optional)

Review Criteria (refer to application, protocol and other submitted documents)

If "No" is selected for any of the items, log a comment in the application.

Application Section 8 – Additional REB and Regulatory Authority Decisions:

1.	No issues have been noted in previous scientific or REB reviews:	Yes☐	No☐

Study Description (Application Sections 3, 4, 5,6 & 7 & Study documentation)

2.	The purpose/rationale for the research is acceptable:	Yes☐	No☐	
3.	Social and scientific value is acceptable:	Yes☐	No☐	
4.	Pediatric studies: the criteria for approving more than minimal risk research have been met and the research presents the prospect of direct benefit to the individual participants	Yes☐	No☐	N/A☐
5.	The study design/methodology is acceptable:	Yes☐	No☐	
6.	The justification for the sample size is appropriate:	Yes☐	No☐	
7.	The selection of participants is equitable:	Yes☐	No☐	
8.	The eligibility (inclusion/exclusion) criteria are acceptable	Yes☐	No☐	
9.	The statistical/data analysis plans are acceptable:	Yes☐	No☐	
10.	The stopping rules are appropriate:	Yes☐	No☐	N/A☐ (none)
11.	The collection, use and retention of biological samples is acceptable:	Yes☐	No☐	N/A☐ (none)
12.	The plan for the return of genetic testing results is acceptable:	Yes☐	No☐	N/A☐ (none)
13.	The use of the proposed surveys, questionnaires, interviews or focus groups is appropriate acceptable.	Yes☐	No☐	N/A☐ (none)

Clinical Trial Information (refer also to the protocol and relevant appended documents)

14.	A description of any anticipated material incidental findings is provided and the plan for disclosing or justification for not disclosing these findings to the participants is acceptable:	Yes☐	No☐

Recruitment (refer also to the protocol and relevant appended documents, Application Section 4)

15.	Recruitment is appropriate:	Yes☐	No☐

Informed Consent (refer also to the protocol)

16.	Request for a waiver of consent is justified and acceptable:	Yes☐	No☐

17. Free and informed consent will be sought:	Yes☐	No☐		
18. Main consent form - study procedures and risks are appropriately described, all required elements are included;	Yes☐	No☐		
21. Assent form - procedures and risks are appropriately described:	Yes☐	No☐		
22. Other consent forms - procedures and risks are appropriately described:	Yes☐	No☐		
23. The plan for communication of the study results is acceptable:	Yes☐	No☐		
Safety	Yes☐	No☐		
24. Risks to participants are minimized:	Yes☐	No☐		
25. The additional safeguards for special populations are appropriate (vulnerability in research/competency):	Yes☐	No☐		
26. The safety monitoring plan is acceptable:	Yes☐	No☐		
27. The data monitoring plan is acceptable:	Yes☐	No☐		
28. Is the description of the DSMB/C or the justification for not having a DSMB/C	Yes☐	No☐		
Privacy & Confidentiality	Yes☐	No☐		
29. provisions to protect the privacy of participants and to maintain the confidentiality of the data are adequate:	Yes☐	No☐		
Funding				
30. Budget/funding is acceptable:	Yes☐	No☐		
31. Potential COI are declared and adequately addressed:	Yes☐	No☐	N/A☐	(none)
Overall	Yes☐	No☐		
32. Risks/benefits ratio are reasonable:	Yes☐	No☐		
33. Respect, justice and concern for welfare are adequately addressed:	Yes☐	No☐		

Areas of concern (*that must be addressed by the PI in order to secure approval*):
Record the modifications that are ***required*** for approval, as well as any recommendations as they should appear in the letter to the PI.