



Relying Site Continuing Review/Study Status Report

Continuing Review Report

Study Site Closure Report

1.0 Study Information

Study Title:	
UTHealth Houston IRB Number:	
Relying Site Name:	
Relying Site PI Name:	

2.0 Current Status of this Study at Relying Site: *(select the best option)*

<p><input type="checkbox"/> Study has not started yet. <i>Explain in comment field below</i></p> <p><input type="checkbox"/> Open for enrollment, but no participant enrolled yet. <i>Explain why in the comment field below</i></p> <p><input type="checkbox"/> Open for enrollment; participants are being enrolled</p> <p><input type="checkbox"/> Closed to enrollment; follow-up with participants and/or data collection still happening</p> <p><input type="checkbox"/> Study is permanently closed to enrollment at this site; all research procedures completed; analysis of identifiable or coded data is still active</p> <p><input type="checkbox"/> Study has been completed.</p> <p>Details/Explanation/Comments:</p>

3.0 Participant Information

<ul style="list-style-type: none">• Total number of participants enrolled during this review period at the relying site. <i>"Enrolled" means the participant signed a consent form or verbally agreed to take part in this study. If this study was granted a waiver of consent, then enrolled means all participants who have been included in the study at this site.</i>	
<ul style="list-style-type: none">• Total number of participants enrolled since this study began at the relying site.	
<ul style="list-style-type: none">• Total number of participants who have completed the study at the relying site	
<ul style="list-style-type: none">• Total number of participants who withdrew/discontinued from the study at this site and reasons for withdrawal. <i>(i.e., did not complete all study procedures)</i>	
Date of Last Subject Contact/Study Activity:	
Details/Explanation/Comments:	

4.0 Informed Consent

Describe the informed consent process for this study. Include details about where and how consent was obtained and how participants reacted when approached.

Waiver of Consent / No Consent at Site

Details:

5.0 Additional Information

5.1 Have all reportable events that have occurred been reported to the lead PI?

Reportable events include adverse events, unanticipated problems, and protocol deviations.

<https://www.uth.edu/cphs/policies/reporting-problems.htm>

Yes

No → *submit the reportable events using the appropriate submission forms.*

N/A – this study has not experienced any events that were reportable during this review period

5.2 At your site, have all children who turned 18 during the course of this study been re-consented with an adult consent document?

Yes

No → *provide more information in the comment field below*

N/A – this study does not enroll children, or this study is conducted under a waiver of consent

Details/Explanation/Comments:

5.3 Have there been any complaints from participants at the relying site?

Yes → *provide details of complaint and resolution in comment field below*

No

N/A – study does not involve contact with participants

Details/Explanation/Comments:

5.4 During the last approval period, did your institution identify any new financial conflict of interest related to this protocol?

Yes

No

Details/Explanation/Comments:

6.0 Additional Details/Comments:

[Empty box for additional details/comments]

7.0 Certification – Completed by the Site PI

I certify that the above-titled research has been conducted in full compliance with the federal regulations and institutional policies governing human subject research.

PI Signature	Signature Date

Submission must be Signed by the Site Principal Investigator