TEXAS Health and Human Services

IRB2 CONTINUING REVIEW OR STUDY CLOSURE

Information for Investigators:

Complete this form **ONLY** if requested by the IRB2 Administrator **or** in the event of study closure. The revised Common Rule of 2018 [see 45 CFR 46.109(f), 46.110, and 46.115(a)(8)] removed the requirement of continuing review for minimal risk research and for full-board research in long-term follow-up and/or data analysis, unless the research is FDA-regulated. IRB2 may require continuing review in special circumstances involving conflicts of interest or noncompliance.

Project Title:			
IRB2 Tracking Number:			
Principle Investigator(s) Contact Information:			
Name:			
Address:			
Phone:		E-mail:	

If study is funded, indicate funding agency:

☐ NOT APPLICABLE: NO FUNDING/SUPPORT RECEIVED FOR THIS PROJECT/ ACTIVITY FROM AN HHS AGENCY OR OTHER SOURCE.

☐ Administration for Children & Families (HHS)

☐ Agency for Toxic Substances & Disease (HHS)

☐ Centers for Disease Control & Prevention (HHS)

☐ Centers for Medicare & Medicaid Services (HHS)

☐ Administration on Aging (HHS)

☐ Office of Inspector General (HHS)

☐ Food & Drug Administration (HHS)

☐ A Texas State Agency (specify): _____

☐ National Institutes of Health (HHS)

☐ Health Resources & Services Administration (HHS)

☐ Office of the Secretary (HHS)

☐ Other (specify): _____

Is this application for Continuing Review or Study Closure?

☐ Continuing Review

☐ Closure

Are you submitting an application for study modifications (to protocol or personnel) at this time?	
☐ Yes (Complete amendment form and submit.) ☐ No ☐ N/A for Study Closure	
Date of initial IRB approval: _____ Study expiration date: _____	
Complete the following items in reference to the period following your last IRB review / renewal	
1. Has the research begun? If no, please explain below.	☐ Yes ☐ No
2. Is enrollment of study participants ongoing? If no, please explain below.	
☐ Yes ☐ No ☐ N/A – Research only includes data request/release or chart review **(go to item #7)**	
3. Date that first subject was enrolled:	
4. Number of participants originally proposed in IRB2 application: _____ Number enrolled to date (TOTAL): _____ Number of subjects enrolled in the past 12 months: _____ Number who withdrew or dropped out: _____ Number who dropped out because of adverse study events: _____	
5. Are study interventions, interactions, and/or treatment ongoing? If no or N/A, please explain:	☐ Yes ☐ No ☐ N/A
6. Was informed consent obtained for all subjects? If no or N/A, please explain:	☐ Yes ☐ No ☐ N/A
Did all participants receive a copy of the signed consent form? If no or N/A, please explain:	☐ Yes ☐ No ☐ N/A

If used, where are signed consent forms stored? Describe site location.

_____

Did you encounter any problems in obtaining consent? If yes, please explain:	☐ Yes ☐ No ☐ N/A

7. Have any changes been made to the following study elements since the initial date of IRB review by IRB2?

Protocol Document	☐ Yes ☐ No
Consent Documents or Procedures	☐ Yes ☐ No ☐ N/A
Questionnaires/Surveys/Other Study Instruments	☐ Yes ☐ No ☐ N/A
Study Interventions or Activities	☐ Yes ☐ No ☐ N/A
Addition/Subtraction of Key Personnel	☐ Yes ☐ No

If you answered "yes" to any of the items above, list the change(s) and the date(s) they were approved by IRB2.

8. Has any new information (e.g., risks of participation, new treatments, alternative approaches, etc.) been identified since the last IRB Approval?

If yes, please describe this new information and how the risk to subjects in your study may be affected by these findings.	☐ Yes ☐ No

9. During the past 12 months, please indicate the following:

Number of serious adverse events: _____ Number of deaths: _____

Were the events listed above promptly reported to the IRB? If No, please explain:	☐ Yes ☐ No ☐ N/A

10. Complete the following table with the names, type of human-subjects training completed, and training completion dates for all currently-approved study personnel (including the PI). Submit copies of training certificates with this application.

Names of Key Personnel	Title of Training (NIH, CITI)	Training Date

11. Provide a detailed summary of all study activities completed to date below (or attached to this document.) Include a timeline for research activities to be conducted in the next 12 months.

12. **For Study Closure Only:** Were you provided with a Waiver of Authorization Letter with your initial IRB approval letter?

If yes, you were provided data that is considered protected health information (PHI) and must be destroyed at the time of study closure. Explain your procedure for destruction of the data provided to you.

☐ Yes ☐ No

13. **For Study Closure Only:** Do you have a final report?

If yes, attach final report, executive summary, publication, or thesis/dissertation abstract.

☐ Yes ☐ No

SIGNATURES

I certify that the statements and attachments concerning this research are true.

_____	_____	_____
Signature of Principal Investigator	Printed Name	Date

REVIEWED AND APPROVED

The information provided has been reviewed and approved by IRB2 for the Protection of Human Subjects in Research for compliance with federal regulations for continuing review.

_____	_____	_____
Signature of Reviewer/IRB Coordinator	Printed Name	Date

If your computer allows email submission, after completing the form click the "Submit" button located below, otherwise submit the form and applicable documentation.

Submit