

IRB2

RENEWAL, CLOSURE, & AMENDMENT PACKET

TO BE COMPLETED AFTER IRB APPROVAL IS OBTAINED

Required Forms for **Renewal OR Study Closure:**

- Renewal or Closure Application with Required Signatures
- Renewal ONLY - Copies of ALL Supplemental Documents Previously Approved by the IRB (e.g., protocol document, instruments, etc.)
- Renewal ONLY - Updated Human Subjects Training if needed (training expires every 3 years)
- Closure ONLY – Final Summary Report

Required Forms for **Amendments:**

- Amendment Application with Required Signatures
- Revised Documents (in track changes or yellow highlighting) for all Revised Documents
- Any new Documents Requiring IRB Review and Approval
- Human Subjects Training for any new Research Personnel being added, if applicable

Tips:

- Use Revision Dates in Header or Footer
- Electronic Signatures Accepted, Scanned Documents w/Signature Preferred

For Assistance Contact:

Abigail Cameron, IRB2 Administrator
abigail.cameron@hhsc.state.tx.us
512.206.5730

INSTITUTIONAL REVIEW BOARD 2

CONTINUING REVIEW – OR – STUDY CLOSURE FORM

Project Title: _____

IRB2 Tracking Number: _____

Information for Investigators:

- Federal regulations require annual review of continuing projects at least once per year.
- If study activities are ongoing (including data analysis and/or writing), you must submit an application for continuing review instead of study closure.
- If ongoing research activities require modifications, please request an amendment form so that changes can be reviewed with your renewal application.
- If you plan to close the study, this means that you have completed all activities including data analysis and the writing of results.

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.
- | | |
|---|--|
| <input type="checkbox"/> Administration for Children & Families (HHS) | <input type="checkbox"/> Administration on Aging (HHS) |
| <input type="checkbox"/> Agency for Healthcare Research & Quality (HHS) | <input type="checkbox"/> Food & Drug Administration (HHS) |
| <input type="checkbox"/> Agency for Toxic Substances & Disease (HHS) | <input type="checkbox"/> National Institutes of Health (HHS) |
| <input type="checkbox"/> Centers for Disease Control & Prevention (HHS) | <input type="checkbox"/> Office of Inspector General (HHS) |
| <input type="checkbox"/> Centers for Medicare & Medicaid Services (HHS) | <input type="checkbox"/> Mental Health & Substance Abuse (HHS) |
| <input type="checkbox"/> Health Resources & Services Administration (HHS) | <input type="checkbox"/> Office of the Secretary (HHS) |
| <input type="checkbox"/> 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 in this packet)

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? Yes No N/A
If no or N/A, please explain:

6. Was informed consent obtained for all subjects? Yes No N/A
If no or N/A, please explain:

Did all participants receive a copy of the signed consent form? Yes No N/A
If no or N/A, please explain:

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

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

7. Have any changes been made to the following study elements since the initial date of IRB review by DSHS 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? Yes No

If yes, please describe this new information and how the risk to subjects in your study may be affected by these findings.

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? Yes No N/A

If No, please explain:

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). Training must be up-to-date. 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? Yes No

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.

13. **For Study Closure Only:** Do you have a final report? Yes No
If yes, attach final report, executive summary, publication, or thesis/dissertation abstract.

SIGNATURES

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

Signature of Principle Investigator

Printed Name

Date

REVIEWED AND APPROVED

The information provided has been reviewed and approved by DSHS Institutional Review Board (IRB#2) for the Protection of Human Subjects in Research for compliance with federal regulations for continuing review.

Signature of Reviewer/IRB Coordinator

Printed Name

Date

IRB2 AMENDMENT REQUEST

PI Name:

IRB2 Tracking No.:

Protocol Title:

1. Are you requesting changes to personnel staff?

Yes No

If yes, list all staff changes below and attach copies of the required IRB training certificate(s) for newly added personnel.

2. Are you requesting changes to: the protocol document, study instruments, recruitment materials, and/or other previously-approved documents?

Yes No

If yes, summarize all proposed changes addressing why these changes are necessary and whether these changes increase or decrease risk(s) to participants. Attach a copy of all revised documents **with track changes and/or yellow highlighting** to illustrate revisions.

3. Are you requesting authorization to include additional data sources or additional years of the same data that you have already been approved to use?

Yes No

If yes, describe the nature of the data being requested and why it is necessary to include these data. State whether data will contain individually-identifiable information and if you will be requesting a HIPAA waiver of consent/authorization. If so, contact: **Abigail.Cameron@hsc.state.tx.us** for the waiver document.

IRB USE ONLY

Approve

Approved with Modifications

Disapproved

Signature of Reviewer/IRB Coordinator

Printed Name

Date