Final Report upon Termination of Project

Instructions:

Submit this form and the information requested before the approval expiration date for the protocol.

Notes:

- To terminate this project, all research related to this protocol must have ceased, including subject enrollment, subject follow-up, and work with identifiable information related to the study subjects, including medical or research records. Data analysis using data collected from study subjects requires IRB approval. If you are performing data analysis, you must submit a Continuing Review application before approval expires.
- Federal Guidelines require a final report upon the termination of a human-participants research study.
- This form will constitute your notice of termination and final report to the IRB.

IRB Study Number: _____

Study Title: _____

Initial Approval Date: _____

Effective Termination Date: _____

Principal Investigator: _____

Telephone # _____ Fax # _____ E-mail address: _____

Co-Investigators Names: _____

(Attach separate sheet if more than four co-investigators) _____

_____

_____

The Study was terminated because (check one)

☐ Research / Study complete

☐ Study was not funded / Funding revoked

☐ Other (specify)

Recruitment / Enrollment

Number of subjects who were screened for the study (completed Consent Form) _____

Number of subjects who met the inclusion criteria and started the study _____

Number of subjects who were dropped or withdrew before completion of the study _____

Number of subjects who completed the study _____

Participant Information

List number of enrolled participants by gender & ethnicity

	White	Hispanic	Black	Native American	Asian	Other	**TOTALS**
MEN							
WOMEN							
						TOTAL ENROLLED PARTICIPANTS	

Participant Withdrawals from Study

Have participants withdrawn from or complained about the study process? ☐ Yes ☐ No

If Yes, describe

Have participants been withdrawn from the study by the Investigator? ☐ Yes ☐ No

If Yes, describe

Adverse Events

Have any serious adverse events occurred because of or coincidental with the protocol during the entire study? (Deaths, serious incidents, significant adverse events) ☐ Yes ☐ No

If Yes, how many? and describe

Have any subjects sought compensation for an injury associated with the study? ☐ Yes ☐ No

If Yes, explain

Confidentiality

Where are the names of all research subjects filed and where are the consent forms kept? If there are no research subjects, indicate no subjects.

Summary of Research Findings

Provide a summary of your research findings. Include a summary of any recent literature, amendments, or modifications to the research since the last full Board review, reports or multi-center trials, and any other relevant information. Also, include information about findings (either good or bad) that should be disclosed to participants in the study. Discuss the rationale for and method of notification to participants. (*Use the box below)*

Principal Investigator's Statement

I certify that the information provided above is true and accurate to the best of my knowledge.

PI Name (Typed)

If researcher is a student, the faculty sponsor's name needs to be typed below.

Faculty Sponsor Name (Typed) Title Date

E-mail the completed form to: steven.lowenstein@dshs.state.tx.us