# Formal Termination of the Research Study or Program Evaluation Form

**Directions: This form must be submitted to HIRB in order to officially end the research study or program evaluation. Complete this form only after ALL participants have completed all phases of the study/project and all data has been collected as per the approved protocol(s).**

1) Principal Investigator Name: _____

2) Title of Project: _____

3) Date of Initial Approval: __/__/____ (mm/dd/yyyy)

4) Date(s) of any approved extensions (please, list dates of all approved extensions:

__/__/____ (mm/dd/yyyy) __/__/____ (mm/dd/yyyy)

__/__/____ (mm/dd/yyyy) __/__/____ (mm/dd/yyyy)

__/__/____ (mm/dd/yyyy) __/__/____ (mm/dd/yyyy)

5) Participant Census:

   a. Number of participants who completed the study/evaluation. _____

   b. Number of participants who withdrew or were discontinued from the study/evaluation. _____

   c. Total number of participants who consented to participating. _____

6) Did any serious adverse events or adverse events occur at any of the research/study sites that <u>have *not* been previously reported</u>? _____ (yes-no)

7) Did any significant protocol violations occur at any of the research/ study sites for this protocol that <u>have *not* been previously reported</u>? _____ (yes-no)

8) If you answered “yes” to either or both question 6 and/or question 7, please list below all previously unreported serious adverse events or protocol violations. **(Note:** *The FDA defines a serious adverse event as any event of an adverse nature that results in any of the following outcomes: death, a life threatening event, in-patient hospitalization or prolongation of an existing hospitalization, persistent or significant disability/incapacity, congenital anomaly/birth defect or important medical event. All must be promptly reported to HIRB to ensure the adequate protection of the welfare of the research subjects.*)

**Statement of Researcher Compliance**

Directions: Please, read the statement below and initial each line to indicate agreement/compliance. Then sign and date the form where indicated. Note: This section of the form can only be completed by the authorized principal investigator, principal researcher, program evaluator on this particular research study.

As Principal Investigator/Principal Researcher/Program Evaluator of this study, I certify each of the following:

_____ all study-related activities have been completed at each study site.

_____ all the information supplied on this form is completely correct; and

_____ no subjects are currently enrolled or actively being followed in this study.

_____ _____

Authorized Researcher Signature Date