**University of North Alabama**

**HUMAN RESEARCH PROTECTION PROGRAM**

**FORM: REQUEST FOR STUDY CLOSURE (INVESTIGATOR)**

**Principal Investigator(s**): Click here to enter text.

**Email:** Click here to enter text. **Telephone:** Click here to enter text.

**College/School/Department:** Click here to enter text.

**Study Title:** Click here to enter text.

**IRB Project number:** Click here to enter text.

**Date of Last Approval:**Click here to enter a date. **Study Expiration Date:**Click here to enter a date.

1. **What is the reason for this closure request? Check only one.**

|  |  |  |
| --- | --- | --- |
|  | **Reasons for Closure** | **Needed Information/Action By PI** |
| [ ]  | 1. All study activities, including data analysis, have been completed. *(If true, this option covers graduating students and persons leaving UA, as well as UA investigators remaining on campus.)*
 | Complete Subject Numbers table below. In COMMENTS provide brief description of major findings. Sign.  |
| [ ]  | 1. Study enrollment and data collection have been completed; data analysis of DE-IDENTIFIED data remains.
 | Complete Subject Numbers table below. Provide any needed comments. Sign.  |
| [ ]  | 1. The study was never initiated.
 | Complete Subject Numbers table. In COMMENTS please explain why study was never initiated. Sign.  |
| [ ]  | 1. The study was initiated but subjects were never enrolled.
 | Complete Subject Numbers Table. In COMMENTS please state how long the study was open and explain why no subjects were enrolled. Sign. |
| [ ]  | 1. Investigator is leaving University, wishes to continue study at new site.
 | Complete Subject Numbers table below. Provide any needed comments. Sign.  |
| [ ]  | 1. Investigator is leaving University, wishes to transfer study to another UNA investigator. *(Covers both cases where PI will continue to work on the study with the new UA PI and where he will not.* *Covers students who leave data for supervisor’s continued use.*
 | Complete Subject Numbers table below. In COMMENTS provide contact information for new investigator. Attach his/her letter of agreement. (See POLICY on Closure for additional information to be submitted by new UA investigator. Sign. |

1. **Final Subject Recruitment and Retention Numbers**

|  |  |
| --- | --- |
| Sample size APPROVED BY IRB |  |
| Number of subjects approached for participation over life of study (to date) |  |
| Number of subjects who declined participation after initial presentation of study (before starting) |  |
| Number subjects screened (if applicable) |  |
| Total number of subjects enrolled |  |
| Number of subjects who have completed study |  |
| Number of subjects who withdrew after starting study |  |
| Number of subjects withdrawn from study by investigator (If any, *please explain)* |  |
| Is recruitment still in progress? (yes-no) |  |

**COMMENTS (***See Table above for needed comments.)*

Click here to enter text.

**Please provide a brief description of the chief study findings if known:**

Click here to enter text.

**SIGNATURES**

NAME of Principal Investigator Click here to enter text.

SIGNATURE of Principal Investigator Click here to enter text.

For **CLOSURE REASON 1**, *your signature certifies that enrollment and follow-up are complete. No further contact with participants/records/specimens is anticipated. Data are no longer identifiable by you, all records of codes or links to data have been destroyed, and/or the data itself have been destroyed.*

Date Submitted: Click here to enter a date.