APPENDIX 4

**OKLAHOMA CHRISTIAN UNIVERSITY**

**HUMAN SUBJECTS RESEARCH CLOSE OUT REPORT**

**A close out report should be submitted when data collection and data analysis are complete.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Responsible Project Investigator (RPI) | | | | |
| **First Name:** | | **Last Name:** | | |
| **Telephone:** | | **Email:** | | |
| **Department:** | **IRB Identifier:** | | | **Expiration Date:** |
| **Complete Title of Research Project:** | | | **Code Name (one word):** | |
| Data on Number of Subject’s Studied | | | | |
| **1. Indicate the number of subjects studied in the space provided.**  1a. What is the total number of subjects enrolled since the last approval? \_\_\_\_\_\_  1b. What is the total number of subjects to date? \_\_\_\_\_\_\_\_  1c. What is the sex and ethnicity distribution of the subjects? Please fill in the table below. (This information is required for all studies that are NIH-sponsored. It is recommended, but not required, that other researchers provide this information.)   |  |  |  |  | | --- | --- | --- | --- | | **Sex** | **Ethnicity** | | | | Males | Black, Non-Hispanic: | Caucasian, Non-Hispanic: | Native American/Alaskan: | | Females | Hispanic: | Asian/Pacific Islander: | Other/Unknown: | | | | | |
| Summary of Results | | | | |
| **2. Please summarize results to date and any relevant information from other studies. Please also discuss any changes in procedures and anticipated risks or benefits. Please attach reprint(s) of published studies, if available.** | | | | |
|  | | | | |
| **3. Were there any medical, legal, or practical difficulties that have been encountered in this time interval of the study aside from adverse events? For example, difficulties would include complaints of subjects, logistic problems of performance, or any difficulties that may pertain to the rights of subjects.**   * Yes **(If yes, please summarize below.)** * No | | | | |
|  | | | | |
| **4. Were there any adverse events encountered during the study?**   * Yes \_\_\_\_\_\_\_\_\_\_\_\_\_**(If yes, please summarize below.)**   Number   * No **(go to 5)**   **4a. Have all adverse events been reported to the IRB?**   * Yes * No **(If no, attach a letter of notification with an explanation)** | | | | |
|  | | | | |
| **5. Did you experience any problems with the consent process?**   * Yes **(If yes, describe the problem(s) and how they were corrected in the space provided. Use additional sheets if necessary.)** * No | | | | |
|  | | | | |
| **6. Please identify the location of the project files in the space provided.** | | | | |
|  | | | | |
| **Responsible Project Investigator** (Must be original signature) **Date** | | | | |