**STUDY CLOSURE FORM**

Instructions and Information: Closure of a protocol means there is not further interaction or contact with participants, no long-term follow-up will be conducted, and no access to personally identifying information will be needed. Study closure is required. Please complete this form, sign, and mail to Chris Fornwalt, Robinwood Suite 229, Room 2224.

|  |  |
| --- | --- |
| **MMC IRB#:** Click here to enter text. | **Study Closure Date:** Click here to enter text. |

|  |
| --- |
| **Principal Investigator:** Click here to enter text. |
| **Study Coordinator:** Click here to enter text. |
| **Title of Protocol:** Click here to enter text. |
| **Sponsor:** Click or tap here to enter text. |

**Section 1:** The following three criteria must be met in order to close a protocol. By checking the boxes below, you agree to the following statements:

|  |
| --- |
|[ ]  No further interaction or contact with participants will take place. |
|[ ]  No long term follow-up is needed. |
|[ ]  No access to personally identifying information will be needed. |
|[ ]  If applicable, Close-out visit from study monitor has been completed. Have all queries been resolved. [ ]  Yes [ ]  No Explain: Click here to enter text. |

**Section 2:** Number of subjects or specimens/data accrued:

|  |
| --- |
| Total number of subjects/specimens/data at all sites: Click here to enter text. |
| Total number of subjects/specimens/data at MMC site: Click here to enter text. |
| Total number of subjects randomized at this site: Click here to enter text. |
| Total number of subjects who completed study at this site: Click here to enter text. |
| Total number of subjects who did not complete study at this site: Click here to enter text. Number of subjects lost to follow-up: Click here to enter text. Number of subjects lost due to AE: Click here to enter text. Other: Click here to enter text. |
| Total number of withdrawals at this site (not including screen fails)**:** Click here to enter text.Name(s) of subject(s) withdrawn: Click here to enter text. Reason for withdrawal: Click here to enter text.  |

**Section 3:** Reason for study closure

|  |  |
| --- | --- |
| [ ]   | Data analysis is complete. |
|[ ]  Lack of enrollment. |
|[ ]  Project no longer funded |
|[ ]  Sponsor closing the study. Reason: Click here to enter text. |
|[ ]  PI is leaving organization. |
|[ ]  Other: Click here to enter text. |

**Section 4:** Please submit a copy of study summary/results, articles, and/or publications regarding

 the completed research or a short summary for this study site.

 Click or tap here to enter text.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Coordinator Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

For IRB Use only

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Chair signature Date