**Study Closure *Final Report Form***

**Obligation of the Principal Investigator – Final Report**

* You may close a human subject research protocol approved by the IRB at any point prior to its expiration date. Please submit within 30 days of the completion of the study.
* Investigators must inform study participants of any significant new knowledge obtained during the course of the research that may affect their future health.
* Researchers are advised to keep study records that include a summary of the research, including findings, and all participant informed consent documents, a minimum of three years past completion of the study. Additional requirements may be imposed by funding agencies, departments, or other entities.
* Do Not Use this Form if:
	+ Any study data being analyzed is identifiable, directly or via a code or linked list of identifiable information.
	+ The final site visit by the sponsor is still pending (industry-sponsored projects).
	+ The funding is still open (an open funding account requires a current IRB approval).
* Submit a continuing review instead, if ongoing IRB authorization is required.

**INSTRUCTIONS: Please answer each of the following questions (if the question is not applicable, enter N/A or None).**

**HSP#** **Study Title:**

**Investigator:** **Contact Person:**

**Most Recent IRB approval date:**

1. **Confirm**

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** | **N/A** |  |
| **[ ]**  | **[ ]**  | **[ ]**  | Is this study closed to enrollment? |
| **[ ]**  | **[ ]**  | **[ ]**  | Have all participants completed all research-related interventions? |
| **[ ]**  | **[ ]**  | **[ ]**  | Have all participants completed all research-related follow-up? |
| **[ ]**  | **[ ]**  | **[ ]**  | Is data analysis complete?(If you answered No and the data being analyzed is identifiable, directly or via a code or linked list of identifiable information, please submit a continuing review instead). |
| **[ ]**  | **[ ]**  | **[ ]**  | Has your sponsored project (funding) been closed? |
| **[ ]**  | **[ ]**  | **[ ]**  | If this is a multi-site study and University is the coordinating institution or the University investigator is the lead investigator, is the study closed at all participating sites? |

1. Total number of participants approved by this IRB to enroll at this site.

1. Total number of participants who have signed the consent document. [ ]  N/A

1. Number of participants enrolled since the beginning of the study.

1. Is there a separate consent form for screening procedures? [ ]  Yes [ ]  No
2. How many subjects have been screened?

* 1. How many screen failures have there been?

1. Total number of subjects who have completed the study:

* 1. Explain any discrepancies in these numbers:

1. Provide a summary of withdrawals from the research (both participant and investigator initiated) since the beginning of the study. Include the number and reasons for withdrawal.

1. Number of participants lost to follow-up since the beginning of the study. Please explain.

1. If any new or unanticipated risks were identified from this study, provide a summary of the risks identified.

1. Have any serious or unexpected adverse events occurred in subjects at this site since the last continuing review report? If yes, describe them and state whether the events have been reported in writing to the IRB and to the sponsor.

1. If any participant experienced unforeseen benefits from participation, provide a summary of the benefits.

1. Please provide a summary of the findings that resulted from the data gathered for this research project.

1. If there have been any concerns or complaints reported since the last review, describe the issue, whether it was resolved, how, and if it has already been reported to the IRB.

1. Has approval for this study expired? [ ]  Yes [ ]  No

If Yes, answer the following questions:

1. Why did approval lapse?

1. Were any additional research participants enrolled or data collected after the expiration date? [ ]  Yes [ ]  No
2. Describe all activities that continued including number of participants involved and any adverse event or incidents that occurred after expiration of approval.

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Signature of Investigator Date