

PARKER UNIVERSITY INSTITUTIONAL REVIEW BOARD

**STUDY CLOSURE REPORT**

* This STUDY CLOSURE REPORT is to be submitted when your study has been completed and patients have completed all required follow-up. For multi-center studies, you may submit this form if all study activity at your site has been completed and the study sponsor expects no additional reports from you.
* Once this document has been submitted, all research activities related to this protocol must end.
* This document will be provided to all IRB members. Please use language that can be understood by both scientific and non-scientific members.
* If a question does not apply to your research protocol, please indicate “not applicable.” Do not leave a question blank.
* If you have questions about how to answer any question, please call the Human Protections Administrator at 214-902-7365.

**Please delete this instruction section from your submission copy**

1. **Form date:**

 Click or tap here to enter text.

1. **Complete project title:**

Click or tap here to enter text.

1. **List the purpose and objectives of the research as stated in the protocol:**

Click or tap here to enter text.

1. **Principal investigator information:**
	1. **Name:** Click or tap here to enter text.
	2. **Telephone:** Click or tap here to enter text.
	3. **Email:** Click or tap here to enter text.
2. **Research Coordinator or Administrator information:**
	1. **Name:** Click or tap here to enter text.
	2. **Telephone:** Click or tap here to enter text.
	3. **Email:** Click or tap here to enter text.
3. **Date of study closure:**

Click or tap here to enter text.

1. **What is the reason for this research study closure? Please check the appropriate box.**

[ ]  **Never activated. Please explain why.** Click or tap here to enter text.

[ ]  **Research Study has been completed as expected.**

[ ]  **Research study terminated early. Date of termination:** Click or tap here to enter text.

 **Provide reason for termination:** Click or tap here to enter text.

[ ]  **Local site closed; study may be active at other locations. Please describe why the study is being closed locally:** Click or tap here to enter text.

1. Participant enrollment information (please use local data)

Table 8

|  |  |  |
| --- | --- | --- |
|  |  | Total sinceOriginal approval |
| 1 | Goal or anticipated enrollment | 0 |
| 2 | Total participants committed | 0 |
| 3 | Total participants committed, but not enrolled (dropped out or excluded before beginning the protocol) | 0 |
| 4 | Total participants completed protocol and all follow-up | 0 |
| 5 | Total participants still receiving research related interventions\* | 0 |
| 6 | Total participants completed protocol, but remain in long-term follow up | 0 |
| 7 | Total enrolled participants off study before completing all research related interventions but remain in long-term follow-up.  | 0 |
| 8 | Total enrolled participants off study before completing all research related interventions and do not remain in long-term follow-up. Exclude deaths. (see line 9) | 0 |
| 9 | Deaths during protocol or follow-up phase | 0 |
|  | Sum of rows 3-9 must equal the number in row 2 | 0 |

What are research related interventions? Research related interventions are defined as anything that is not standard medical care being performed for clinical purposes no matter the level of risk.

\*Patients who decide to discontinue their participation in the research intervention but agree to continue being followed for the research study (e.g., continue to have follow-up visits and information is reported to the sponsor) should be listed in line 7. Patients who decide to discontinue their participation in the research intervention and are not followed for the research study any longer should be listed in line 8. Patients in row 7 who die during the research study should be moved from row 7 to row 9 and should be recorded in both Table 9 and 10 below.

1. **Participants off study:** Provide the following information for all participants in row 7 and 8 in Table 8.

|  |  |  |  |
| --- | --- | --- | --- |
| Patient Study ID # | Date Consented | Date of event | Reason for withdrawal |
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1. **Serious, Adverse or Unexpected Events:** Please list all serious or unanticipated adverse events along with all deaths (counted in row 9 in Table 8) that have been reported to the sponsor and to the GHS-IRB for participants enrolled locally. Include all participants since original approval. (Please add rows if needed)

|  |  |  |  |
| --- | --- | --- | --- |
| Study ID # | Consented | Event |  |
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1. **Please describe any results available to date, if any (such as study endpoints reached).**

Click or tap here to enter text.

**Principal Investigator Assurance Statement**

My electronic signature, that will accompany the submission of this Study Closure Report and supporting documents to the Parker University Institutional Review Board, certifies that activity on the Research Protocol has ended. I will report to the IRB, at any time in the future, additional Research Study information received that may impact subject(s) safety or rights. NOTE: This may include delayed adverse events that may place subject(s) at continued risk or revelations of research misconduct.

Principal Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_