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Study Closure Final Report

Return this form to: Baptist IRB [Baptist.IRB@bmhcc.org](mailto:Baptist.IRB@bmhcc.org) (Baptist IRB)

Note: This form is locked and will accept inputs only in check boxes and text boxes indicated by °°°°°, which will expand as necessary to accommodate text. The completed form should be saved with a unique file name.

Use this form for sponsored studies conducted at multiple sites, including BAPTIST if:

* The study sponsor has formally notified the principal investigator that the study has closed.

Use this form for studies conducted only at BAPTIST if:

* All subjects must have completed all treatment visits and all follow-up visits.
* Data analysis has been completed.

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| I. General Information |

| Title of study: | | | | IRB Number: | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| (a) Sponsor: | | | | | | | | | |
| (b) Principal Investigator: | | | | | | | | | |
| (c) Person completing this form:  Position:  E-mail:  Tel: | | | | | | | | | |
| (d) Dates: Approved Last Review: Closure Date: | | | | | | | | | |
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| **II. Report of Activity** | | | | | | | | | |
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|  | How many subjects were enrolled locally in this protocol? | | | | | | | |
|  | Since the study was last reviewed, have any research subjects withdrawn or been withdrawn from participation?  If *yes*, please describe the circumstances of each withdrawal. (Use a separate sheet if necessary) | | | | Yes | | | No |
|  | Since the study was last reviewed, has anything happened in the execution of the protocol that affects the conduct of this study? If *yes*, explain (Use a separate sheet if necessary) *A statement from the Data Safety Monitoring Board/Data Monitoring Committee or sponsor indicating that it has reviewed interim findings satisfies this requirement.* | | | | Yes | | | No |
|  | Since the study was last reviewed, has anyone complained or expressed a concern about the research to you or to anyone associated with the research?  If *yes*, please describe each occurrence and how the issue was resolved. | | | | Yes | | | No |
| (e) | | Answer the following questions only if the study was sponsored. | | | |  |  | |
|  | | Was the study closed before it met the objectives stated in the protocol?  If *yes*, please explain briefly why the study was closed at this time. | | | | Yes | No | |
|  | | Did all the subjects enrolled at this site complete the active and follow-up phases of the study? If *no*, please explain why.  Please explain what arrangements have been made to end participation of any subjects who are still enrolled in the protocol. | | | | Yes | No | |
| (f) | | Answer the following questions only if the study was initiated and carried out at a Baptist entity. | | | | | | |
|  | | Did the study meet its objectives? If *no*, please explain why. | | | | Yes | No | |
|  | | Did all the enrolled subjects complete the active and follow-up phases of the study? If *no*, please explain why.  Please explain what arrangements will be made to terminate the participation of any subjects who remain enrolled in the protocol. | | | | Yes | No | |
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| **III. Study Personnel** | | | | | | | | |
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|  | Since the study was last reviewed, have any changes occurred in the professional personnel participating in the study? If *yes*, please explain | | | | Yes | | | No |
|  | Since the study was last reviewed, have the licenses, certifications or professional privileges of any personnel participating in the study been restricted or modified? If *yes*, please explain | | | | Yes | | | No |
|  | Since the study was last reviewed, have there been any changes in the financial relationship between any member of the research team and the sponsor? If *yes*, please explain | | | | Yes | | | No |
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| **IV. Safety Reports & Audits** | | | | | | | | |
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|  | Since the study was last reviewed, has there been a Data Safety Monitoring Board/Data Monitoring Committee (DSMB/DMC) report or interim safety report received?  If *yes*, submit a copy of the report. | | | | Yes | | | No |
|  | Have any serious or unanticipated events involving risks to subjects or others occurred locally that have not been reported to the Baptist IRB?  If *yes*, complete attached sheet for local events. | | | | Yes | | | No |
|  | Since the study was last reviewed, has the study been monitored or audited *locally*?  If *yes*, attach findings on a separate sheet, *if available*. | | | | Yes | | | No |
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| 1. **Supporting Documentation** | | | | | | | | |
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| **If this study was sponsored please provide a copy of the closure or termination letter from the sponsor** | | | | | | | | |
| **Signature of Principal Investigator or Person Submitting Form** | | | | **Date** | | | | |
| 1. **IRB Action** | | | | | | | | |
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| **Accept**, no modifications required. Study may be closed  **Request additional information** (see letter to investigator) | | | | | | | | |
| **Signature of IRB Chair** | | | | **Date** | | | | |