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Study Closure Final Report

Return this form to: Baptist IRB 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:       |
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| (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|  | Since the study was last reviewed, have any research subjects withdrawn or been withdrawn from participation?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** |