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|  | **Institutional Review Board** **570-887-4885** Lori Robinson, IRB Coordinator, Guthrie Foundation |

Dec 2019 **Final Report – Study Closure**

*Use this form for sponsored studies conducted at multiple sites, including GUTHRIE if:*  
   The study sponsor has formally notified the principal investigator that the study has closed.  
  
*Use this form for studies conducted only at GUTHRIE 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** | | | | | | | |
| IRB Number:           Protocol ID: | | | | | | |
| Title of study: | | | | | | |
| (a)   Sponsor: | | | | | | |
| (b)   Principal Investigator: | | | | | | |
| (c)   Person completing this form: | | | | | | |
| (d)   Dates:       Initial Approval:   Closure Submision **:** | | | | | | |
| **Reason For Closure:** | | | | | | |
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| **II.      Report of Activity** | | | | | | |
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|  | (a) | How many subjects were enrolled at Guthrie sites in this protocol? | | | | |
|  | (b) | Since the study was last reviewed, have any research subjects withdrawn or been withdrawn from participation?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 |
|  | (c) | 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 |
|  | (d) | 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) | | 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 |
|  | (f) | | Did all the subjects enrolled at Guthrie 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 |
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|  | **III.     Study Personnel** | | | | | |
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|  | (a) | Since the study was last reviewed, have any changes occurred in the professional personnel participating in the study? If *yes*, please explain | | | Yes | No |
|  | (b) | 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 |
|  | (c) | 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 |
|  | | | | | | |
|  | **IV.    Safety Reports & Audits** | | | | | |
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|  | (a) | 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 |
|  | (b) | Have any serious or unanticipated events involving risks to subjects or others occurred locally that have not been reported to the Guthrie IRB? If *yes*, complete attached sheet for local events. | | | Yes | No |
|  | (c) | 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 |
|  | | | | | | |
|  | **Supporting Documentation** | | | | | |
|  | If this study was sponsored please provide a copy of the closure letter from the sponsor. | | | | | |
| **Signature of Principal Investigator or Person Submitting Form**    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | **Date**   \_\_\_\_\_\_\_\_\_\_\_\_ | | |
| IRB Number:           Protocol ID: | | | | | | |
| Title of study: | | | | | | |
| **Closure Approved**, no modifications required. \_\_\_\_\_\_  **Request additional information** (see letter to investigator) \_\_\_\_\_\_ | | | | | | |
| ***Conflict of interest statement:***  I do not have a personal, scientific, or financial interest in this research.   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of IRB Chair or designee Date** | | | | | | |