|  |  |
| --- | --- |
|  | **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.

|  |
| --- |
| **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:**  |
|   |
| **II.      Report of Activity**  |
|    |
|    |  (a)  | How many subjects were enrolled at Guthrie sites in this protocol?    |
|    |  (b)  | Since the study was last reviewed, have any research subjects withdrawnor been withdrawn from participation?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 expresseda 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 protocolIf *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-upphases of the study? If *no*, please explain why.      Please explain what arrangements have been made to end participationof any subjects who are still enrolled in the protocol.    | Yes **[ ]**    |  No[ ]   |
|    |
|    | **III.     Study Personnel**  |
|    |
|    |  (a)  | Since the study was last reviewed, have any changes occurred in theprofessional personnel participating in the study? If *yes*, please explain   | Yes **[ ]**    |  No[ ]   |
|    |  (b)  | Since the study was last reviewed, have the licenses, certifications orprofessional privileges of any personnel participating in the study beenrestricted or modified? If *yes*, please explain   | Yes **[ ]**    |  No[ ]   |
|    |  (c)  | Since the study was last reviewed, have there been any changes in thefinancial relationship between any member of the research team and thesponsor?  If *yes*, please explain    | Yes **[ ]**    |  No[ ]   |
|    |
|    | **IV.    Safety Reports & Audits**  |
|    |
|    |  (a)  | Since the study was last reviewed, has there been a Data SafetyMonitoring Board/Data Monitoring Committee (DSMB/DMC) reportor 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 orothers 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** |