|  |  |  |
| --- | --- | --- |
| **FORM 9**  **CLOSURE/FINAL REPORT FORM** | | |
|  | | |
| **PROTOCOL CODE:** | | |
| **PROTOCOL TITLE:** | | |
| **PRINCIPAL INVESTIGATOR:** | | |
| **PROTOCOL (INITIAL) APPROVAL DATE: <**DD/MM/YYYY**>** | | |
| **Email:** | **Telephone:** | **Mobile:** |
| **STUDY SITE: <**name and address**>** | | |
| **SPONSOR:** | | |
| **SPONSOR CONTACT PERSON:** |  |  |
| **Email:** | **Telephone:** | **Mobile:** |
| 1. Study Arms: | | |
| 1. Summary of Recruitment:   \_\_\_\_\_ Accrual ceiling set by REC  \_\_\_\_\_ New participants accrued since last review  \_\_\_\_\_ Total number of participants accrued since protocol began  \_\_\_\_\_ No. of participants who are lost to follow up  \_\_\_\_\_ No. of participants withdrawn from the study  \_\_\_\_\_ No. of participants who experienced SAEs/SUSARs  Number of participants who completer the study: \_\_\_\_\_\_\_ | | |
| 1. Amendments to the original protocol (including dates of approval): | | |
| 1. Summary of onsite SAEs reported: | | |
| 1. Summary of participants’ complaints or grievances documented regarding conduct of study: | | |
| 1. Summary of benefits to participants: | | |
| 1. Summary of indemnifications of study related injury (If Applicable): | | |
| 1. If terminated early, specify reason for termination: | | |
| 1. Progress reports submitted (with dates of approval): | | |
| 1. Duration of the study (months): | | |
| 1. Informed consent form used (with version no./date) and attach most recent version: | | |
| 1. Study objectives and summary of results: | | |

|  |  |
| --- | --- |
| DATE OF LAST REVIEW: | |
| SIGNATURE OF PI: | |
| DATE: | |
| RECEIVED BY: | |
| RESPORT SUBMISSION DATE: (to be filled out by REC) | |
| **FOR REC USE ONLY**  **COMMENTS OF PRIMARY REVIEWER** (i.e. compliance with the terms of the approved protocolincluding post- approval review requirements, and overall assessment of risks against benefits in the conduct of study) | |
| **RECOMMENDED ACTION:**   * APPROVE * REQUEST INFORMATION: (specify) * RECOMMEND FURTHER ACTION: (specify) * PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE | |
| **PRIMARY REVIEWER** | Signature: |
| Name | Date: |