**Progress Report Form / Continuing Review Form**

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:** *This form is required for submission of progress report. Obtain an electronic copy of this form and encode all information required in the space provided. Print the report in A4 size paper; then date and sign this form before submission.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **MMMC-RERC CODE:** | | | | | | |
| **STUDY PROTOCOL TITLE:** | | | | | | |
| **PRINCIPAL INVESTIGATOR:** | | | | | | |
| **STUDY PROTOCOL APPROVAL DATE:** <dd/mm/yyyy> | | | | | | |
| **Email:** | | **Telephone:** | | | **Mobile:** | |
| **STUDY SITE NAME:** | | | | | | |
| **STUDY SITE ADDRESS:** | | | | | | |
| **SPONSOR:** | | | | | | |
| **SPONSOR CONTACT PERSON:** | | | | | | |
| **Email:** | | **Telephone:** | | | **Mobile:** | |
| **REPORT SUBMISSION DATE:** <dd/mm/yyyy> | | **DATE OF START OF STUDY:**  <dd/mm/yyyy> | | | | |
| **ACTION REQUESTED:**  Renewal: New participant accrual to continue  Renewal: Enrolled participant follow up only  Progress Report  Other (specify): | | | | | | |
| 1. Number of participants required from the site: | | | | | | |
| 1. Total number of patients randomized in the study: | | | | | | |
| 1. Number of screen failed in the study: | | | | | | |
| 1. Number of patients still enrolled (active) in the study: | | | | | | |
| 1. Number of patients actively withdrawn from the study: | | | | | | |
|  | | Number of reports submitted | | Date of Submissions | | Action of the RERC |
| 1. Amendments | |  | |  | |  |
| 1. SAE/SUSAR Reports (attach line listing if necessary) | |  | |  | |  |
| 1. Progress Reports | |  | |  | |  |
| 1. Protocol Deviations/ violation reports | |  | |  | |  |
| 1. Summary of unanticipated risks (others than SUSAR) and issues documented in the conduct of study: | | | | | | |
| 1. Summary of participants’ complaints or grievances documented regarding conduct of study: | | | | | | |
| 1. New information (literature or in the conduct of the study) that may significantly change the risk-benefit ratio: | | | | | | |
| 1. Summary of indemnifications (If applicable): | | | | | | |
| 1. Summary of study materials used (for non-clinical research): | | | | | | |
| 1. List of informed consent form used (version/date) and attach most recent version: | | | | | | |
| **DATE OF LAST REVIEW:** <dd/mm/yyyy> | | | | | | |
| **SIGNATURE OF PI:** | | | | | | |
| **DATE SUBMITTED:** <dd/mm/yyyy> | | | | | | |
| **RECEIVED BY:** | | | | | | |
|  | | | | | | |
| **RECOMMENDATIONS (for MMMC-RERC use only)** | | | | | | |
| **COMMENTS OF PRIMARY REVIEWER** (i.e. compliance with the terms of the approved protocol including post-approval review requirements, and overall assessment of risks against benefits in the conduct of study) | | | | | | |
| **RECOMMENDED ACTION:**  APPROVED  DISAPPROVED  REQUEST INFORMATION: (specify)  RECOMMEND FURTHER ACTION: (specify) | | | | | | |
| **PRIMARY REVIEWER** |  | Signature |  | | | |
| Date: <dd/mm/yyyy> |  | Name | <Title, Name, Surname> | | | |