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| **REC PROTOCOL CODE NO.:** | | |
| **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. Number of participants who completed the study: \_\_\_\_\_\_\_\_\_\_\_  |  |  |  | | --- | --- | --- | | 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accrued since protocol began | |  |  | No. of participants who are lost to follow up | |  |  | No. of participants withdrawn from the study | |  |  | No. of participants who experienced SAEs/ SUSARs | | | |
| 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: | | |
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| **DATE OF LAST REVIEW:** |
| **SIGNATURE OF PRINCIPAL INVESTIGATOR:** |
| **DATE:** |
| **RECEIVED BY:** (Name of NCMH-REC Staff) |
| **REPORT SUBMISSION DATE:** (to be filled out by the NCMH-REC) |

**NCMH-REC USE**

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| **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:**  APPROVE  REQUEST INFORMATION: (specify)  RECOMMEND FURTHER ACTION: (specify)  PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE | | | |
| **PRIMARY REVIEWER** |  | Signature: |  |
| Date: |  | Name: |  |