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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: \_\_\_\_\_\_\_\_\_\_\_

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| 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|  |  | No. of participants withdrawn from the study |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 |

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| 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: |  |