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| --- | --- | --- | --- | --- |
| Date of submission |  | REC Protocol Number |  | Sponsor Protocol Number |
|  |  |  |  |  |
|  |  |  |  |  |
| Principal Investigator |  | Email / Mobile Number |  | Sponsor |
|  |  |  |  |  |

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| --- | --- |
| Title of Study |  |

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| --- | --- | --- | --- |
| Study Site |  | Date of Initial Approval |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Items to be Amended | | List of Amendments\* | | | Reasons | | | | | Reviewer’s Comments  (REC use only) |
|  | |  |  |  |  |  | |  | |  |
|  | |  |  |  |  |  | |  | |  |
|  | |  |  |  |  |  | |  | |  |
| **\*Indicate pages in the document where the amendment is found. Underline or highlight the amendments done in the documents** | | | | | | | | | | |
| Name & Signature of  Principal Investigator |  | | | | | | Date: | |  | |

**Received by:**

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| --- | --- | --- | --- | --- | --- |
| REC Staff |  | Signature |  | Date |  |

**Type of review:**

Expedited review

Full board review

**FOR NCMH-REC USE**

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| Assessment by Primary Reviewers | **Type of amendments:**  **Minor**  **Major**  **Does the amendment increase the risks to participants?**  **Yes**  **No**  **Does the amendment increase the benefits to participants?**  **Yes**  **No**  **Is there favourable benefit/ risk ratio?**  **Yes**  **No** | **Comments** | **Recommendation** |

**Primary reviewer:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name of Reviewer: |  | Signature |  | Date |  |

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| --- | --- | --- |
| **REC Final Decision** | Approve  Request further information / modification  Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
|  |  | |
| **Maurice L. Sañosa, MD, FPCGM** |  |  |
| NCMH-REC Chairperson | Signature: | Date |