**Study Protocol/Informed Consent Amendment Submission Form**

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:** *A study protocol amendment is a written description of a change(s) to or formal clarification of a protocol and/or informed consent documents. Favorable opinion or approval should be obtained from the MMMC-RERC that issued the ethical clearance or approval prior to the implementation of an amendment. Multiple amendments classified under ONE type of review (expedited or full review) can be submitted in one form.*

**INSTRUCTIONS TO THE PRIMARY REVIEWER:** *Please provide assessment points to each amendment made in the study protocol. If applicable, comment whether these changes will add additional risk or benefit to the study population.*

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| **MMMC-RERC CODE:** | | | | | | | | |
| **STUDY PROTOCOL TITLE:** | | | | | | | | |
| **APPROVAL DATE:** | | | | | | | | |
| **PRINCIPAL INVESTIGATOR:** | | | | | | | | |
| **Email:** | | **Telephone:** | | | | | **Mobile:** | |
| **STUDY SITE NAME:** | | | | | | | | |
| **STUDY SITE ADDRESS:** | | | | | | | | |
| **SPONSOR:** | | | | | | | | |
| **SPONSOR CONTACT PERSON:** | | | | | | | | |
| **Email:** | | **Telephone:** | | | | | **Mobile:** | |
| **AMENDMENT SUBMISSION DATE:** | | | | | | | | |
| **1. NO. OF AMENDMENT/S:** | | | | | | | | |
| **2.STATE NATURE OF PROTOCOL AMENDMENTS (Cite study protocol section and page where amendment is found)** | | | | | | | | |
| Amendment No. | Nature of Amendment/s | | | | | Justification of Primary Investigator | | Assessment of Primary Reviewer |
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| **3. STATE THE NATURE OF INFORMED CONSENT AMENDMENT (Cite informed consent section and page where amendment is found)** | | | | | | | | |
| Amendment No. | Nature of Amendment/s | | | | | Justification of Primary Investigator | | Assessment of Primary Reviewer |
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| **SIGNATURE OF PRINCIPAL INVESTIGATOR**: | | | | | | | | |
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| 1. **TYPE OF REVIEW**: *(to be fill up by MMMC-RERC)*    1. **EXPEDITED** REVIEW FOR AMENDMENTS THAT:  * Do not involve changes in study populations * Do not involve the collection of stigmatizing information * Do not change approved use of anonymized or archived samples * Do not involve further recruitment of participants * Involve study protocols previously classified under expedited review * Are administrative in nature (such as contact details of study personnel) * Do not materially affect the risk-benefit ratio of the approved protocol or increase risks to study participants   1. **FULL BOARD REVIEW** (for any amendments not cited under EXPEDITED REVIEW) | | | | | | | | |
| **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  MINOR MODIFICATION TO THE STUDY PROTOCOL , SUBJECT TO EXPEDITED REVIEW AT THE LEVEL OF THE PANEL CHAIR  MAJOR MODIFICATION TO THE STUDY PROTOCOL, SUBJECT TO FULL PANEL REVIEW  DISAPPROVED | | | | | | | | |
| **PRIMARY REVIEWER** | | |  | Signature |  | | | | |
| Date: <dd/mm/yyyy> | | |  | Name | <Title, Name, Surname> | | | | |