**Study Protocol Non-compliance (Deviation or Violation) Report**

**INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:** *This form refers to the requirements in ICH-GCP Sections 4.5: COMPLIANCE WITH PROTOCOL and 5.20: NONCOMPLIANCE. Obtain an electronic copy of this form and encode all information required in the space provided. Multiple deviations/violations classified under ONE type of review (expedited or full review) can be submitted in one form. Print the report in A4 size paper; then date and sign this form before submission****.***

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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:** |
| **REPORT SUBMISSION DATE:** <dd/mm/yyyy> | | |
| 1. **NATURE OF REPORT**    1. **MINOR PROTOCOL DEVIATION** (*nonsystematic protocol noncompliance with minor consequences, in terms of its effect on the participant’s/subject’s rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature*)    2. **MAJOR PROTOCOL DEVIATION OR PROTOCOL VIOLATION***(persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients’ safety at risk)* | | |
| 1. **DESCRIPTION OF REPORTED DEVIATION/VIOLATION:** | | |
| 1. **STATE THE POTENTIAL RISK OF THE DEVIATION/VIOLATION TO THE STUDY PARTICIPANT/S:** | | |
| 1. **DESCRIPTION OF INVESTIGATOR CORRECTIVE ACTION:** | | |
| 1. **SPONSOR ASSESSMENT OF SEVERITY:**    1. **MINOR**    2. **MAJOR** | | |
| 1. **DESCRIPTION OF SPONSOR CORRECTIVE ACTION:** | | |
| **DATE OF DEVIATION/VIOLATION:** <dd/mm/yyyy> | | |
| **REPORTED BY:** | | |
| **DATE OF REPORT:** <dd/mm/yyyy> | | |
| **PRINCIPAL INVESTIGATOR SIGNATURE:** | | |

**RECOMMENDATIONS** *(for MMMC-RERC use only)*

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| **COMMENTS OF PRIMARY REVIEWER** | | | |
| **RECOMMENDED ACTION:**  Acknowledged/No further action required  Study to continue but will monitor compliance  Request information  Recommend further action  For site visit  Suspend the study until the following are met:   * Additional information is made available * MMMC-RERC recommendations are implemented by the Principal Investigator and considered satisfactory by the MMMC-RERC   Terminate the study on the basis of one or more of the following:   * SAE reports indicate harm to participants * Breach of a previously approved conduct of research. * Major changes, deviations or amendments of the approved protocol without approval by the MMMC-RERC * Revision in the Informed Consent form without approval by the MMMC-RERC. * Fraud. | | | |
| **PRIMARY REVIEWER** |  | Signature |  |
| Date: <dd/mm/yyyy> |  | Name | <Title, Name, Surname> |