**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)*
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| 1. **DESCRIPTION OF REPORTED DEVIATION/VIOLATION:**
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| 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.
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| **PRIMARY REVIEWER** |  | Signature  |  |
| Date: <dd/mm/yyyy> |  | Name | <Title, Name, Surname> |