**Deviation/Violation Reporting Form**

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| **Title of Proposal:**  |  |
| **Principal Investigator(s)**  |  |
| **MUBASREC Protocol No.**  |  |
| **Date of Deviation/Violation:** |  |
| **Study Participant number (where applicable)** |  |
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| **Protocol Deviation/Violation Assessment** |
| Did the protocol deviation/violation put the safety and well-being of the participant(s) at risk? [ ]  Yes [ ]  NoHas the Sponsor been notified of this event? [ ]  Yes [ ]  NoWill the subject continue his/her participation in the study? [ ]  Yes [ ]  No [ ]  N/AWas the deviation planned or unplanned? [ ]  Planned\*\* [ ]  Unplanned(\*\*please provide prior approval from the sponsor) |

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| **Protocol Deviation/Violation Description and Reason** |
| Please provide a description of the deviation/violation:  |
| Please explain the reason for the deviation/violation (Root cause analysis):  |
|  |
| **Corrective and Preventive Action (CAPA)** |
| Please describe what action(s) you have taken to prevent recurrence of this deviation/violation in the future and attach supporting documents:  |

Signature (PI or designee): Date: