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**Protocol Deviation Report (PVR)**

**INSTITUTIONAL ETHICS COMMITTEE (IEC)**

**PROJECT DETAILS**

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| --- | --- |
| **IEC Reference Code** |  |
| **NMRR number** |  |
| **Study Title** |  |
| **Principal Investigator** | **Name** |
| **Telephone Number** | **Email** |
| **Sponsor** | **Name****Address** |
| **Telephone Number** | **Email** |
| **MREC *(if applicable)*** | **Approved Study Site(s)** |
| **Total number of subjects in MREC approved study site(s)** | **Number of study arms** |

**A. DEVIATION DETAILS**

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| 1. **Describe how the research deviated from the approved protocol, including dates and circumstances and the responsibilities of individual researchers**
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| 1. **Detail any effects upon human participants, animals or the environment resulting from or related to the deviation and all remedial actions taken in response**
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| 1. **Detail how you propose to ensure that the above deviation/s will not reoccur**
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**B. PRINCIPAL INVESTIGATOR DECLARATION**

By submitting this **Protocol Deviation Report**, I, the **Principal Investigator**, declare that:

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| **[ ]**  | To my knowledge, after making all necessary inquiries, the information contained in this report is true and accurate; |
| **[ ]**  | All deviations from the approved protocol have ceased; and |
| **[ ]**  | **I acknowledge that a deviation from an approved protocol will be treated as a breach of the UCSI IEC Ethics Approval and further action may be taken in relation to this reported deviation.** |

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| **PI Name** |  |
| **Email** |  |
| **Contact number** |  |
| **Date** |  |
| **Signature & stamp** |  |