|  |  |  |  |
| --- | --- | --- | --- |
| **HREC/ ERM Reference Number:** |  | **Site Name/Number:** |  |
| **Protocol Title:** |  | **Protocol ID** |  |
| **Principal Investigator:** |  | **Contact details** |  |
| **Study Contact Person:** |  | **Contact details** |  |
| **Ref** **No.** | **Date of Deviation/ non-serious breach** | **Date Identified** | **Identified by** **(name & position of the research personnel)** | **Number of participants impacted****(if applicable)** | **Participant Study ID****(if applicable)** | **Deviation Description1** | **Site Impact & Action Taken2** | **Initials****(the person completing the entry)** |
| 1 |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

Instructions:

1. Deviation Description
* Including details of any changes investigational products (does or frequency interruptions), changes to consent procedures, changes to visit schedule, use of external services (pathology, imaging), and etc.
1. Site Impact & Action Taken
* Including details if the deviation impacts on study validity, participant safety and privacy, and outcome measures.