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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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.