|  |  |
| --- | --- |
| **Behavioural Protocol Deviation** | For Internal Use Only |
| UnivRS Internal ID:  Date Received: Click here to enter a date. |

**Key Information**

|  |
| --- |
| UnivRS Internal Project ID# or Ethics ID# (Beh xx-xxx):\* |
| Principal Investigator Name:\* |
| Project Title:\* |

# Project Status

|  |  |
| --- | --- |
| Is this project open to recruitment:\* | Yes  No |
| Indicate the number of participants currently in the study:\* |  |

**Deviation Information**

|  |
| --- |
| Date of protocol deviation:\* Click here to enter a date. |
| Date the site became aware of the protocol deviation:\* Click here to enter a date. |
| Provide a detailed description of the protocol deviation: \* |
| Number of participants affected by the protocol deviation:\* |
| Provide an explanation of how any participants affected by the protocol deviation will be informed: \* |
| Describe the plans to address the problems resulting from the deviation and to prevent similar deviations in the future: \* |

|  |  |
| --- | --- |
| Have any similar protocol deviations been reported to the Research Ethics Board:\* | Yes  No |
| If yes, please explain: | |
| Does the protocol deviation jeopardize the safety of research participants, the research efficacy, or data integrity: \* | Yes  No |
| If yes, please explain: | |

**Declaration by Principal Investigator**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **The Principal Investigator assumes full responsibility for the information presented in this report.**  **The Principal Investigator or delegate confirms that they:**   * have reviewed the protocol deviation and its safety implications**;** * have assessed the relationship of the event to the project; * attest to the accuracy of this report.  |  |  | | --- | --- | | Date form completed: Click here to enter a date. | | | Name of person who completed this form: |  |   If this form is submitted on behalf of the Principal Investigator:   |  |  | | --- | --- | | is authorized to prepare and submit this form on behalf of the Principal Investigator | | | Authorized person contact information: | | | Email: | Phone: | |

**Document(s)**

Provide a list of documents that are being submitted along with this report: