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

**Key Information**

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

# Project Status

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

**Deviation Information**

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| 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: \* |

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| 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**

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

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| 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:

|  |
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|       is authorized to prepare and submit this form on behalf of the Principal Investigator |
| Authorized person contact information: |
| Email:       | Phone:       |

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**Document(s)**

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