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

**Questions marked with an** \* **are mandatory.**

**Key Information**

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| UnivRS Internal Project ID# or old Ethics ID # (Bio xx-xxx):\* PI Name: \*      Protocol Number (if applicable):      Project Title: \* |

**Local Project Status**

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| --- | --- |
| Open to Recruitment: \* | [ ]  Yes [ ]  No |
| Participant(s) on study intervention: \*  | [ ]  Yes [ ]  No |
| Participant(s) in follow-up stage: \* | [ ]  Yes [ ]  No |
| No participant(s) enrolled: \* | [ ]  Yes [ ]  No |
| Provide additional details as applicable:       |

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**Deviation Information (Only submit a deviation if it meets at least one of the criteria below)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| --- | --- |
| Jeopardizes research participants’ safety: | [ ]  Yes [ ]  No |
| Jeopardizes research efficacy: | [ ]  Yes [ ]  No |
| Jeopardizes research data integrity: | [ ]  Yes [ ]  No |
| Jeopardizes research participants’ privacy: | [ ]  Yes [ ]  No |
| Led to a sponsor-approved waiver to participant eligibility criteria: | [ ]  Yes [ ]  No |
| Change in the approved process for obtaining consent (i.e. improper translation, current ICF not implemented): | [ ]  Yes [ ]  No |
| Led to a serious adverse event (ensure you attach a completed Local Unanticipated Problem report form to this submission): | [ ]  Yes [ ]  No |

If submitting a report that does not meet at least one of the above criteria, provide justification as to why it is being submitted: Detailed description of deviation: \*  |

**Reporting Timelines**

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| Date of Event: \* Click here to enter a date.Date the project team became aware of the event: \* Click here to enter a date.If the deviation was not submitted to the REB within reporting timeline (within 15 calendar days; 7 if led to death or life-threatening adverse event), explain the lapse: |

**Action(s)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Check all that apply:**

|  |  |
| --- | --- |
| Is any corrective action necessary?: | [ ]  Yes [ ]  No |
| If yes, describe:  |
| Has the participant(s) been informed?: | [ ]  Yes [ ]  No |
| Has the sponsor been notified?: | [ ]  Yes [ ]  No |
| If no, please explain: |

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**Declaration by Principal Investigator:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **The Principal Investigator assumes full responsibility for the information presented in this report. The Principal Investigator or delegate confirms that he/she:*** has reviewed the protocol deviation and its safety implications**;**
* has assessed the relationship of the event to the project;
* attests to the accuracy of this report.

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| Date the form was completed: Click here to enter a date. |
| Name of Person who completed the form: |       |

If form submitted on behalf of the PI:

|  |
| --- |
|       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, as applicable:

**REB Chair Response (Internal use only)**

|  |  |  |  |  |  |  |
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| No further action required:  | [ ]  Yes [ ]  No |
| Referred to Full Board: | [ ]  Yes [ ]  No |
| Requested more information:  | [ ]  Yes [ ]  No |

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