|  |  |
| --- | --- |
| **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**

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

**Local Project Status**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | 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: | | |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | 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**

|  |
| --- |
| 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: | | |

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

**Document(s)**

Provide a list of Documents that are being submitted along with this report, as applicable:

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

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