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| **Biomedical Local Adverse Event/**  **Unanticipated Problem Report Form** | **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):  Title: \* |

**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: | | |

**Reporting Criteria**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | **Only submit local adverse events that meet the definition of an unanticipated problem (i.e. unexpected, related and involving greater risk). If you submit a report that does not meet the criteria, it will not be acknowledged by the REB.** | | | The nature of the unanticipated problem is unexpected in terms of nature, severity or frequency: \* | Yes  No | | The nature of the unanticipated problem is related or possibly related to participation in the research: \* | Yes  No | | The nature of the unanticipated problem suggests that the project places participants or others at greater risk of harm, including physical, psychological, economic or social harm, than was previously known or recognized: \* | Yes  No | |

**Description of Event**

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| Type of Report: \* Choose an item.  If follow-up: Follow-up report number:  Date of Event: Click here to enter a date.  Date the project team became aware of the event: Click here to enter a date.  SAE Report Number OR Participant ID Number:  Event Summary: |

**Actions Taken as a Result of Event:**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | Hospitalization: | Yes  No | | Change to study treatment: | Yes  No | | Suspension of study treatment: | Yes  No | | Discontinuation of study treatment: | Yes  No | | Study blind broken | Yes  No | | Other | Yes  No | | Provide additional details as applicable: | | |

**Participant Outcome**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | Complete resolution: | Yes  No | | Ongoing/unresolved: | Yes  No | | Partial recovery: | Yes  No | | Disability or impairment: | Yes  No | | Caused congenital malformation/birth defect | Yes  No | | Death: | Yes  No | | Other: | Yes  No |   Provide additional details as applicable: |

**Declaration by Principal Investigator:**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **The Principal Investigator assumes full responsibility for the information presented in this report and confirms that he/she:**   * has reviewed the unanticipated problem and its safety implications**;** * has assessed the relationship of the problem 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 | | Request more information | Yes  No | |