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| **Biomedical Non-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 # (if applicable):      Title: \* |

**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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**Reporting Criteria**

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| **Only submit events that meet BOTH criteria A and B** |
| **A:** The event meets the definition of an unanticipated problem **(i.e. unexpected and related/possibly related and suggests greater risk of harm): \*** | [ ]  Yes [ ]  No |
| **B:** The event requires:\* |
| * Change to the research AND/OR:
 | [ ]  Yes [ ]  No |
| * Change to consent form AND/OR:
 | [ ]  Yes [ ]  No |
| * Immediate notification to participants for safety:
 | [ ]  Yes [ ]  No |

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**Description of Event**

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| AE description: \* Choose an item.Date the project team became aware of the event: Click here to enter a date.Actions to be taken at local site: |

**Required AE Information**

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| **Attached documentation must include ALL of the following:*** Description of the event(s)
* All previous safety reports concerning similar adverse events.
* Analysis of the significance of the current adverse event(s) in light of previous reports.
* Description of proposed research changes, consent form changes or other corrective actions to be taken.

**Note that a change to study materials (e.g. protocol, consent form, documents given to participants) must be submitted as an amendment as soon as available.** |

**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.

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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:

|  |
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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, as applicable:

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

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| No further action required.  | [ ]  Yes [ ]  No |
| Referred to Full Board. | [ ]  Yes [ ]  No |
| Request more information  | [ ]  Yes [ ]  No |

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