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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**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | 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 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 | |

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

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