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| **Biomedical**  **Additional Reportable Events/Documents** | **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: \*  Event Category: \* Choose an item. |

**Project Status**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | Participants will be affected by the event/document(s): \* | Yes  No | | Provide additional details as applicable:  If applicable, summarize and provide reasons for the addition of document(s): |  | |

**Reportable Event Information**

|  |  |  |
| --- | --- | --- |
| |  |  | | --- | --- | | This is a reportable event: \*  If yes, complete the following: | Yes  No |   Date the Event was identified by project team members: Calendar  Describe the event:  Describe the project team’s response to the event: |

**Declaration by Principal Investigator:**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **The Principal Investigator assumes full responsibility for the information presented in this report and confirms that he/she:**   * has assessed the relationship of the event/document(s) 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 items for review/acknowledgement: