**Linfield University**

**IRB Incident Report Form**

**Part 1: General Information**

1. IRB Approval Number:

2. Project Title:

3. Principal Investigator(s):

4. Co-investigator(s) *- if you are a student, you must include your advisors name*:

5. Is this research being funded by an external funding agency:

**NO**

**YES (specify)**:

**Part 2: Incident Information**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. | Names of individuals involved: | | | | |  | |
| 2. | Location of the incident: | | | |  | | |
| 3. | Date(s) of incident: | |  | | | | |
| 4. | Incident involved: | | | | | | |
|  | | Drug/Device | | Procedure | | | |
|  | | Treatment | | Intervention | | | |
|  | | Other: | | | | | |
| 5. | Severity of Incident: | | | | | | |
|  | | Mild | | Moderate | | | Severe |

|  |  |
| --- | --- |
| 6. | Describe the incident in detail: |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 7. | Was this incident an anticipated risk described in the initial protocol application and informed consent documents? | | | |
|  | | YES | NO |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 8. | In your judgment, was the event caused by procedures associated with this protocol? | | |
|  | | Related | Possibly related |
|  | | Not related | Possibly not related |
|  | | Not information to judge | |

|  |  |
| --- | --- |
| 9. | If “related” or “possibly related” to the research, explain what procedures were already in place to minimize or reduce the risk of this event. |

**Part 3: Treatment Information (if applicable)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | 6. | Individual’s recovery was: | | | | |  | Complete | | Moderate | | |  | Minimal | | Not resolved at this time | | |  | Other: | | | | |  | | | | | | 7. | In your judgment, should the informed consent process or any part of the protocol be modified as a result of this event? | | | | |  | | YES (Submit a [MODIFICATION FORM](http://web1.boisestate.edu/research/compliance/irb-forms.shtml)) | | NO | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. | Date of treatment: |  | | |
| 2. | Name of individual(s) who received treatment: | | |  |
| 3. | Name of individual(s) who provided treatment: | | |  |
| 4. | Location of treatment: | |  | |
| 5. | Describe the treatment provided to the participant(s) in detail: | | | |

**Part 4: Additional Information**

|  |  |
| --- | --- |
| 1. | Other than this report, have any other reports been submitted to other offices/departments regarding this event? Indicate where and when these reports have been submitted. |

|  |  |
| --- | --- |
| 2. | Additional Information: |

**Part 5: Signatures**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | |  | |  | |  | |  | |
| **Principal Investigator (PRINT)** |  | | **Signature** | |  | | **Date** | |
|  |  | |  | |  | |  | |
|  |  | |  | |  | |  | |
| **Co-PI/Faculty Adviser (PRINT)** |  | | **Signature** | |  | | **Date** | |

Submit completed form to the IRB chair (irb@linfield.edu).