**IRB INCIDENT REPORT FORM**

* All incidents of injury or other adverse effects experienced by participants must be reported by the principal investigator to the Institutional Review Board, through the Research Compliance Office within 48 hours after the event.
* **This page, signed by the principal investigator, may be submitted to the Research Compliance Office as a scanned PDF to jdowning@cocc.edu:**

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| --- | --- | --- | --- | --- | --- |
| **SECTION A: Protocol Information** | | | | | |
| 1. | IRB Approval Number: | |  | | |
| 2. | Project Title: |  | | | |
| 3. | Principal Investigator(s): | | |  | |
| 4. | Co-Principal Investigator(s): | | | |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SECTION B: 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 |

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

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

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

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| 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. |

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| **SECTION C: Treatment Information (if applicable)** | | | | |
| 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: | | | |

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| --- | --- | --- | --- | --- |
| 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)](https://www.cocc.edu/departments/instruction/research-compliance/institutional-review-board/files/irb-modification-report-form-jan-2019-update.docx) | | NO |

|  |  |
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| **SECTION D: 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. |

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| 2. | Additional Information: |

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| **SECTION E: Signatures** | | | | | | | | | | |
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| **Principal Investigator (PRINT)** | |  | | **Signature** | |  | | **Date** | | |
|  | |  | |  | |  | |  | | |
|  | |  | |  | |  | |  | | |
| **Co-PI/Faculty Adviser (PRINT)** | |  | | **Signature** | |  | | **Date** | | |