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|  | **INSTITUTIONAL REVIEW BOARD (IRB)***IRB Event Report Form*  *Application For Reporting Adverse Events & Protocol Deviations* |
| Instructions for Submitting the Report*This form is used for reporting unanticipated problems involving risks to subjects or others, adverse events, protocol**deviations, participant complaints, and other problems. Reports need to be submitted as soon as possible after the PI learns of the event. Serious events need to be submitted within 5 business days and non-serious events need to be reported within 10 business days. If you have any questions, please contact the IRB Coordinator.* |
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| **I. ADMINISTRATIVE DATA** |  |
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| 1. **Project Title:**
 |       |
| 1. **IRB Approval #:**
 |       |  |
| 1. **Department:**
 |       |
| 1. **Principal Investigator Information:**
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| PI Name *(must be faculty)*: |       | Email Address: |            |
|  PI Department Address:  |       | Fax #: |       |
|  Campus Phone #: |       | Other Phone #: |       |
| 1. **Funding Source:**
 |       |
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| **II. PROTOCOL INFORMATION** |  |
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1. **Type of Report**

Indicate the type of report that you are filing.
[ ]  Adverse Event or Injury

[ ]  Participant Complaint

[ ]  Problem or Finding

[ ]  Protocol Deviation

1. **Date of the Event**

Provide the date of the event.

1. **Participant Identifier Number**

Provide the participant's identifier number. Do not use the participant's real name or medical record number. If not applicable, put "N/A" as your response.

1. **Personnel Involved**Provide the names and positions of the project personnel that were involved in the event. If no project personnel were involved, put "N/A" as your response.

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| **Names** | **Position** |
|       |       |
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1. **Assessment of the Event/Problem**

Indicate your assessment of the event or problem below (select all that apply):
[ ]  Serious Event

[ ]  Non-Serious Event

[ ]  Unexpected Event

[ ]  Related to the Study

[ ]  Unrelated to the Study

[ ]  Unsure if Related to the Study

[ ]  Not Applicable

1. **Source of the Report**

Indicate if the report relates to an internal local event (research site is under FIU’s oversight) or an external non-local event (research site is under an external non-FIU IRB’s oversight).

[ ]  Internal (Local Event)

[ ]  External (Non-Local Event)

1. **Location of Event**

Indicate location where event occurred.

1. **Description of the Event/Problem**Describe in detail the event or problem being reported. If you are reporting a protocol deviation, explain the deviation and why/how the deviation occurred. Do not include participants’ personally identifiable information.

1. **Status of Participants**Indicate if the participant(s) is/are still involved in the study.

[ ]  Still in the Study

[ ]  No Longer in the Study

[ ]  Not Applicable

1. **Status of Research Recruitment**Indicate if participants are still being recruited into this study.

[ ]  Ongoing

[ ]  Completed (or Stopped)

[ ]  Not Applicable

1. **Status of Interventions/Interactions**

Indicate if participants are still being recruited into this study.

[ ]  Ongoing

[ ]  Completed (or Stopped)

[ ]  Not Applicable

1. **Impact on Participants**

Indicate if the event resulted in a violation of the participant’s rights, safety, or welfare.

[ ]  Yes

[ ]  No

If Yes, explain how the event resulted in a violation of the participant's rights, safety, or welfare:

1. **Other Reporting**

Indicate where else you will be reporting this event to (check all that apply).

[ ]  Sponsor of Study

[ ]  Food and Drug Administration (FDA)

[ ]  Collaborating Investigators

[ ]  Data Safety Monitoring Board

[ ]  Not Applicable

[ ]  Other:

1. **Actions to Take**

As a result of the event, indicate the corrections/changes that you will be taking (if applicable) to resolve the current issue and/or prevent similar events from occurring in the future (check all that apply):
[ ]  Modification to Protocol/Study Procedures

[ ]  Modification to Level of Risk

[ ]  Modification to Consent Form

[ ]  Provide Additional Information to Participants

[ ]  Re-Consent Current Participants

[ ]  Research will be Voluntarily Placed on Hold

[ ]  Re-Training of Project Staff to Prevent Future Occurrences

[ ]  No Action is Planned

[ ]  Other Action Planned:

If taking corrective action, explain the specific corrections/changes that will be made:

1. **Additional Comments**

Provide any additional comments and/or attachments that you would like to include in reference to this event/problem.

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| **III. AFFIRMATION OF INVESTIGATOR** |  |

As the Principal Investigator, I am confirming that the information I have provided in this form is accurate and true.

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Signature Date