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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:** | | | | | | |
| 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