Form 108: Promptly Reportable Information Form (PRIF)

Office of Research Integrity

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<https://www.fau.edu/research-admin/research-integrity/human-subjects-irb/>

**INSTRUCTIONS**: New information meeting the criteria below must be **reported to the FAU IRB. Please refer to Policy 10.3.5, “Reporting Serious Adverse Events and Unanticipated Problems” Appendix A for reporting guidelines.**

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| **A. STUDY INFORMATION** |  |
| Novelution #:     Complete Title of Study:       |
| FAU Principal Investigator:       | Phone:       | E-mail:       |
| Primary Contact if other than PI:       |  |  |

Initial Report Follow-Up Report

Study Open to Accrual Study Closed to Accrual

**B. TYPE OF EVENT**

# New or increased risk or a safety issue

* Any increased risk of harm or actual harm experienced by a subject or other individual, which in the opinion of the investigator, is unexpected and related or possibly related to the research procedures
* New information that indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk (ex: an interim analysis, data safety monitoring report, IND safety report, publications indicating a new risk, sponsor report, or investigator finding)
* An investigator brochure, package insert, or device labeling revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
* Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
* Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
* Breach of confidentiality
* Any other information that affects the safety of subjects or the conduct or integrity of the research

# Protocol deviation/violation, if it:

* Harmed a subject or others or that indicates subjects or others might be at increased risk of harm
* Resulted in a participant being enrolled who did not meet eligibility criteria
* Resulted in research procedures taking place before a correct version of the signed consent was executed
* Was made without prior IRB approval to eliminate an apparent immediate hazard to a subject
* Affects the overall integrity of the research data

# Unresolved subject complaint

**Incarceration of a subject in a research study not approved to involve prisoners Allegation of noncompliance or finding of noncompliance**

**Unanticipated adverse device effect**

* Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects (21 CFR 812.3(s))

# Suspension or premature termination by the sponsor, investigator, or institution Audit, inspection, or inquiry by a federal agency

**Written reports from a federal agency (e.g., FDA Form 483) State medical board or hospital medical staff actions**

**Other information that the sponsor/lead site/ others has directed the PI to report to the IRB.**

**C. EVENT DESCRIPTION**

Local Non-Local

Date of Event:       Date FAU PI Became Aware of Event:

Subject ID#:      Subject Age:       Subject Sex:

**1**. Provide detailed description of the event as applicable, including:

1. a description of the event, including whether this is an internal event involving a patient/ subject, staff, student, affiliate, other individual, or an external event;
2. how and/or why it occurred;
3. timeline for the event, including timing of study treatment/dosing/research intervention, start and stop dates of relevant research interventions;
4. treatment or follow-up provided to subject as a result of the event;
5. subject’s relevant medical history;
6. current status of the subject.

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1. Describe why, if applicable, in your opinion the event is unanticipated and possibly/probably/definitely related.

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1. Describe the outcome of the event on the study (ex: increased risk of harm to subject or others, violation of subject’s rights, safety, or welfare, effect on study integrity, change of status of subject in study, etc.).

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1. Describe necessary protocol changes, including treatment or procedures that will be taken to address the problem, and the corrective actions to prevent future occurrences, if applicable. (For example, changes will be made to the consent form to include this new risk, the protocol will be updated, or study staff will be reeducated on the study procedures.) If none, justify. Changes must be submitted to the IRB for approval before implementation.

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1. Is the event resolved? Yes No N/A

If no, please file a follow-up report to the IRB once more information is available.

**Responsible Project Investigator Assurance**:

By signing this IRB serious adverse event / unanticipated event report electronically I, the Responsible Project Investigator, assure the Board that this report has been thoroughly reviewed and completed. I understand that any requested modifications are not to be instituted until final approval from the IRB is secured. I will only use the stamped, approved IRB consent and/or assent documents for use with human subjects. Furthermore, if any further problems involving human subjects occur, I will immediately notify the IRB.

**Department Chair and/or College Representative Assurance:**

By signing this IRB serious adverse event / unanticipated event report electronically I, the Department Chair and/or College Representative, assure the Board that I have thoroughly reviewed this report.