FLORIDA ATLANTIC UNIVERSITY

DIVISION OF RESEARCH

SUBJECT: Reporting Serious Adverse Events and Unanticipated Problems	**Policy Number:** 10.3.5	**Effective Date:** March 24, 2022
	Supersedes: October 20, 2014	**Pages: 6**
	Responsible Authorities: Vice President for Research Assistant Vice President, Research Integrity Institutional Review Board	

I. Background

Federal regulations require researchers to promptly report to the IRB all serious adverse events (SAEs) and unanticipated problems (UPs) involving risk to human subjects or others that occur during an IRB-approved research protocol. In addition, researchers may need to report these events to the study sponsor, institutional officials, and the appropriate regulatory agencies, when applicable.

II. Purpose

This policy provides researchers with guidance on reporting serious adverse events or unanticipated problems involving risk to human subjects or others during an IRB-approved research protocol.

III. General Statement

Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although they can and do occur in social- behavioral research. Many adverse events are expected based on previous studies in the literature and are outlined in the informed consent document. These do not need to be reported to the IRB. However, if an adverse event is a) serious; b) unexpected in nature, severity, and frequency; c) a potential risk to human subjects or others; and d) a result of the research, it meets the definition of a "serious adverse event." Serious adverse events require a closer level of scrutiny and must be reported to the IRB.

Similarly, "unanticipated problems" that are not physical or medical in nature can also arise in the context of a research study. For example, a breach of confidentiality or an error in how human subjects data has been analyzed, are both unanticipated problems that do not show up as a physical or psychological symptom in the subject. However, if they are unexpected, and can potentially pose a risk to the human subjects involved, or others, they must be reported to the IRB.

Both serious adverse events and unanticipated problems, whether they occur in a clinical trial, social/behavioral research study, or other human subjects study, may signal that risks to subjects are greater than expected. They may also trigger modifications to the research protocol, informed consent, or other information presented to the research subjects. In some cases, they may even require that a

study be suspended or terminated. To make appropriate decisions concerning the protection of human subjects in research, the IRB requires these events to be reported appropriately. The principal investigator (PI) of any research study is responsible for reporting these events.

IV. Definitions

Adverse Event: any untoward or unfavorable medical occurrence (physical or psychological), cognitive, or affective response in a human subject, including any a

report(s) of an adverse event or unanticipated problem *that represents serious and/or unexpected events*, the DSMB should send a report to the PIs and study sponsor in a prompt manner. It is the responsibility of the PI to review the report and submit a Serious Adverse Event/Unanticipated Problem report to the IRB within the appropriate timeframes.

e) Providing additional information about newly recognized risks to previously enrolled subjects;
f) Suspending enrollment of new subjects;
g) Suspending approval of the research; or
h) Terminating approval of the study (via a convened IRB meeting).

The Research Integrity office will be responsible for:

- Promptly forwarding SAE/UP reports to the IRB Chair or designee.
- Communicating to the PI in writing the IRB's actions/decisions regarding an SAE/UP that he/she reports to the Board.
- Documenting the IRB protocol file appropriately.
- Promptly communicating in writing to appropriate institutional officials, funding agencies, and regulatory agencies, the details of any unanticipated problems involving risks to subjects or others; b) any serious or continuing noncompliance with 45 CFR 46, 21 CFR 56, or the requirements or determinations of the IRB; and c) any suspension or termination of IRB approval, within one month.

VII. Procedures

Follow all reporting requirements for the IRB providing oversight for the project. If FAU is IRB of Record, the PI must adhere to the following for all sites. If another IRB is serving as IRB of Record, follow reporting requirements for the lead institution and FAU. Unless specifically noted, use FORM104, "Promptly Reportable Information Form". If a report is submitted by the PI beyond the timelines outlined by this policy, a written explanation of the delay must be included in the submission to the IRB.

See Appendix A for reporting timelines and process.

VIII. Policy Renewal: As needed

IX. References

OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events
45 CFR §46.103 (b)(5)(i)
21 CFR 312.32, 312.66
21 CFR 56.108 (b)(1), 812.150

POLICY APPROVAL
Initiating Authority

Signature: Date:

Appendix A: Serious Adverse Event and Unanticipated Problems Reporting Timelines

Event	Reporting Timeline	Additional Information
• Written report of any death or a life-threatening experience occurring to a subject enrolled in a study approved by the FAU IRB	Within 3 Calendar Days of awareness	Event must be related or possibly related to the protocol intervention; if the PI is uncertain, report it within the IRB requested timeframe until further conclusive evidence becomes available
• Written report of any other SAE or UP occurring within a study approved by the FAU IRB and occurring at an FAU site. • Written report of an SAE or UP occurring at an		