

Mccaslin, Gailine P

From: Mahoney, Michael P
Sent: Tuesday, January 23, 2018 3:00 PM
To: irbmail-l@lists.ufl.edu
Cc: Mccaslin, Gailine P
Subject: Important info: Reporting "Unanticipated Problems"

Attention researchers:

External auditors recently identified that our research community needs to be better informed about "Unanticipated Problems". This is significant because researchers are required to promptly report "Unanticipated Problems" to the IRB.

Unanticipated Problems are any incident, experience, or outcome that meets all three of the follow criteria:

1. **Unexpected** in terms of nature, severity, or frequency given (a) the research procedures and (b) the characteristics of the subjects being studied.
2. **Related or possibly related** to participation in the research.
3. Suggests subjects or others are at a **greater risk of harm** (physical, psychological, economic, or social harm) than was previously known or recognized, even if no specific harm has yet occurred.

Examples include but are not limited to:

- Malfunctioning of research equipment that results or could result in risk to subjects or others.
- Breach of confidentiality, such as losing laptop that stored subjects identifiable private information.
- Loss of research data, such as paper records lost or destroyed, or electronic records lost if a hard drive crashes.
- Incorrect labeling, dosing, or dispensing of study medication even if there is no indication of harm.
- Regular adverse events that are unexpected, related/possibly related, and place subjects or others a greater risk of harm – regardless of the severity of the adverse event. Examples could include less serious adverse events that are occurring more frequently than anticipated, or are not described in the protocol or informed consent form.

Helpful links:

- This issue is described in greater detail in the IRB's Investigator Guideline, "*Unanticipated Events Reporting*": <http://irb.ufl.edu/wp-content/uploads/Unanticipated-Events-Reporting.pdf>
- IRB Policy HRP-112 "Reportable Events": <http://irb.ufl.edu/wp-content/uploads/HRP-112-POLICY-Reportable-Events.pdf>
- myIRB Researcher Manual with instructions on how to submit the Unanticipated Problem for review (page 27): <http://irb.ufl.edu/wp-content/uploads/myirbresearchermanual.pdf>

What do you need to do if you identify an Unanticipated Problem?

- Any Unanticipated Problems that you identify must be promptly reported to the IRB via myIRB.
 - Directions on how to do this are on page 27 of our myIRB Researcher Manual (<http://irb.ufl.edu/wp-content/uploads/myirbresearchermanual.pdf>) or you can contact the IRB office for assistance.
- You must list the Unanticipated Problem on the Cumulative Adverse Event Table submitted with your future Continuing Reviews.

Questions? Please contact the IRB:

- IRB-01: (352) 443-9444 ufirb-l@lists.ufl.edu

- IRB-02: (352) 392-0433 irb2@ufl.edu
- IRB-03: (904) 244-9427 IRBSubmission@jax.ufl.edu