

Regulation: There are plenty of regulations requiring that Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO) must be reported. The procedures and concepts are identical to evaluation of adverse events but the realm of problems is bigger than the realm of adverse events.

The risk of encountering an unanticipated problem is reduced by anticipating it in the first place and having the professionals and resources to respond.

What is a **Problem**? (Do not report)

We generally can recognize problems as they occur daily. Most problems are anticipated; we have trained for them and have procedures to deal with them.

- An adverse event is, by definition, a problem.
- The computer froze and the data was lost but there was a back-up
- The surveys to be administered are still back at the office.
- You or the subject arrived at the right time – on the wrong day .
- The subject had a headache and didn't show up. (also a deviation).

What is an **Unanticipated Problem**? (Report on IRC form 4.35)

This sub-set of problems is why we have skilled and experienced professionals who are equipped to deal with surprises. There was no mention of it in the protocol, the description of the previous studies. There is no plan in place.

- The completed surveys were left at the coffee shop
- The laptop was stolen
- The question that seemed innocuous caused a response.
- An interviewer at a subject's home was raped.

What is an **Unanticipated Problem Involving Risk to Subjects**? (Report on IRC form 4.35)

Did the authors mean risk of harm or actual harm? Report both. In this area we incorporate a seriousness (not trivial but enough to require action or medication or costs to subject or investigator) and relatedness. Relatedness might not be clear until it happens again or until a trend emerges. Harms can be physical, legal, social, emotional or financial (loss of insurability).

- The laptop was stolen and it had identifiable sensitive information.
- The question that seemed innocuous caused hysterical sobbing and reportable information.
- Taking a child from a classroom results in a student becoming seriously marginalized.
- It is determined that several subjects were incapacitated by the serious headache.
- A Serious AE is, by definition a problem that involves serious risk.

What is an **Unanticipated Problem Involving Risk to Others**? (Report on IRC form 4.35)

Others is a big category including colleagues, current or future subjects, their relatives, and people relying on the results of the study.

- Other interviewers were at risk and are now sent out only in pairs.
- The database on the computer is of subjects and people who were on a contact list.
- A subject is exposed to an infectious disease and then exposes her whole family

