
NEW YORK UNIVERSITY SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD

Date: June 1, 2007

Re: Reportable Events Policy

Dear Sponsors,

In accordance with federal regulations governing Institutional Review Boards (45 CFR 46 and 21 CFR 50 and 56) and Guidance on Reportable Events form both the Office of Human Research Protection, the Food and Drug Administration and the New York University School of Medicine Institutional Review Board will review only unanticipated problems involving risks to subjects or others.

Reportable events include events that involve harm or injury (physical, psychological, social or economic) that is unexpected events and occurred as a result of participation in a research study.

While there are many terms to define a given type of reportable event (e.g., serious adverse event, adverse event, adverse experience, etc.), the NYU SoM IRB uses the following single definition for an IRB-reportable event:

Reportable Event is an unanticipated problem involving risks to participants or others (Unanticipated Problem) and any event or information that (1) was unforeseen and (2) indicates that the research procedures caused harm to participants or others or indicates that participants or others are at increased risk of harm.

The following definitions are used by NYU SoM:

Unanticipated - An event is unanticipated y when its specificity or severity is not consistent with the current investigator brochure, protocol, consent form, package insert or label; or unanticipated in its frequency, severity, or specificity.*

Related - An event is related to a research procedures if in the opinion of the principal investigator, it was more likely than not to be caused by the research procedures or if it is more likely that not that the event affects the rights and welfare of current participants.

Harmful - caused harm to participants or others, or placed them at increased risk of harm. The harm does not have to be a direct harm to be reportable. The harm, as assessed by the PI or monitoring agent, has presented increased risk (e.g, losing a laptop with subject data). Additionally, the harm does not have to be the harm to subjects it could involve risk to others (researchers, technicians, bystanders, the public, etc.).

Note: non-medical events (e.g, breach of confidentiality, emotional breakdown, loss of insurance, etc.). if unanticipated - would also be reportable to the IRB.

Adverse Event - Is any physical, psychological or social harm to subjects during the course of research.

The NYU SoM requests that researchers decide if the event is RELATED, UNANTICIPATED AND HARMFUL before submitting a reportable event to the IRB.

The NYU SoM IRB will require expected events to be reported at the time of continuing review for the particular project. We ask researchers to submit expected events in an aggregate or summary format. Please make sure to assist our researchers by providing this information on a regular basis.

Thank you for taking the time to read this letter and for your continued support of our research endeavors at NYU SoM. Should you have any questions, please contact either myself or the IRB Assistant Director, Ms. Helen Panageas at the phone number listed above.

Sincerely,



Elan Czeisler
Director