

Office of Academic Affairs
Human Subjects Protection Program

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SUBJECT: Reportable Events Policy

In accordance with federal regulations 45 CFR 46 and 21 CFR 56.108(b) (1), 312.53(c) (1) (vii), and 312.66) and Guidance on Reportable Events from both the Office of Human Research Protection and the Food and Drug Administration, the UMDNJ Institutional Review Board will review **only unanticipated problems** involving risks to subject or others; or a **death** in an interventional study for which a UMDNJ IRB is the IRB of record that occurred within 30 days of the intervention or interaction.

An Unanticipated Problem is an event that fulfills **all three** of the following criteria:

1. It is **unexpected** in terms of nature, severity or frequency, given the research protocol, investigator's brochure, IRB-approved informed consent document, product labeling and other sources of information, and given the characteristics of the subject population being studied (expected natural progression of subjects' disease, disorder or condition or predisposing risk factor profiles)
2. It is **related or possibly related** to participation in the research (i.e. is there a definite or reasonable possibility that the incident, experience or outcome may have been caused by the research drug/device or research procedures?)
3. The event can potentially **place the research subjects or others at a greater risk** of harm (including physical, psychological, economic or social harm) than was previously known or recognized).

Unanticipated problems or a death should be reported in accordance to the following timeframe:

1. **Within 24 hours of discovery** - A death in an interventional study for which a UMDNJ IRB is the IRB of record.
2. **Within one week of discovery** – An unanticipated problem which is a serious adverse event
3. **Within two weeks of discovery** – All other unanticipated problems.

Researchers must make a determination that the event is unexpected, unanticipated, and potentially impacts risk before submitting a reportable event to the IRB. Event reports not fulfilling the above criteria will be returned to the investigator but may be submitted at time of continuing review in an aggregate or summary format.