

IN THE KNOW

BULLETIN OF THE TUFTS SBER IRB MEDFORD CAMPUS

ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

Did you know that Adverse Events and Unanticipated Problems must be reported to the IRB office within seven days of the occurrence?

Please use the *Adverse Event Reporting* form or the *Unanticipated Problem Reporting* form that can be found on the website at:
<http://www.tufts.edu/central/research/IRB/index.htm>

ADVERSE EVENTS

- Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (can be both physical and/or psychological).
- Example: A participant becomes upset by fear provoking stimuli, even though this was anticipated and mentioned in the consent form.

UNANTICIPATED PROBLEMS

- Include any incident, experience, or outcome that meets **all** of the following criteria:
 1. Unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents and the characteristics of the subject population being studied *and*
 2. Related or *possibly related* to participation in the research (there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research) *and*
 3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.
- Example: Participants become upset by stimuli, but this was not expected.