# A Guide for Reporting Adverse Events to the UHSRC

These guidelines are adapted from those drafted by the Department of Health and Human Services Office of Human Research Protections (OHRP), tailoring them to the types of studies most often conducted at EMU (i.e., non-biomedical research). Some examples have been lifted verbatim from the OHRP guidelines. See http://www.hhs.gov/ohrp/policy/advevntguid.html for a more thorough discussion of the OHRP guidelines on reporting of Adverse Events and Unanticipated Problems.

**Adverse Events** are any negative or untoward outcome experienced by a subject during the course of participation in a research study. Adverse Events do not have to be caused by study procedures. Examples of Adverse Events include eyestrain headaches after computer tasks, distress at answering questions about a traumatic event, or bruises at the site of a blood draw. Adverse Events should be reported at the annual renewal of approval (continuing review).

**Serious Adverse Events** are **serious** negative outcomes experienced by a subject and include death, life-threatening outcomes, hospitalizations (initial or prolonged), disability or permanent damage, congenital anomaly/birth defect, required intervention to prevent permanent impairment or damage (as in with a device), or other important medical or psychological events. Serious Adverse Events must be reported to the UHSRC as soon as possible but no later than 24 hours after the PI learned of the event. Serious Adverse Events are to be reported using the Event Reporting Form in IRBNet.

**Unanticipated Problems** are any events that are **unexpected**, **related or possibly related to the research**, and **may increase risk to subjects or others**. Unanticipated Problems may or may not happen directly to the subject and include extreme distress at being asked to recall a happy or neutral memory, stolen or lost laptop with data or data files, researcher misconduct, inadvertently identifying a subject in publication, a change in FDA labeling of a drug or device used in the research, and subject complaints that cannot be resolved by the research team. Unanticipated Problems must be reported to the UHSRC as soon as possible but no later than 24 hours after the PI learned of the event. Unanticipated Problems are to be reported using the Event Reporting Form in IRBNet.

**Deviations** occur when the approved protocol is not followed **exactly** as approved. Deviations can be minor or major. Minor deviations include over-enrollment of subjects and allowing UHSRC approval to lapse. Major deviations include (but are not limited to) research misconduct, using an incorrect or expired consent form, not conducting all research assessments as scheduled, enrolling from a subject population that has not been approved, and collecting data that have not been approved. Deviations must be reported within 24 hours of discovery by the PI. Deviations are to be reported using the Event Reporting Form in IRBNet.