Adverse Event Definitions

Adverse events: are untoward or undesirable experiences associated with research, including any abnormal sign (for example, abnormal physical exam or laboratory finding), 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.

Adverse events may be the result of:

- the interventions and interactions used in the research,
- the collection of identifiable private information in the research,
- an underlying disease, disorder, or condition of the subject, and/or
- other circumstances unrelated to the research.

Unexpected Adverse Event: Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:

- the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the IRB-approved documents (e.g., applicable investigator brochure, current protocol narrative, current informed consent document), and (b) other relevant sources of information, such as product labeling and package inserts; or
- the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject’s predisposing risk factor profile for the adverse event.

Serious Adverse Event: is any adverse event temporally associated with the subject’s participation in research that meets any of the following criteria:

- results in death,
- is life-threatening situation,
- requires inpatient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability/incapacity,
- results in a congenital anomaly/birth defect,
- any other adverse events based upon the Researcher’s medical judgment, that may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For MMC’s Guidance on Serious Adverse Events see SOP RR 404-B.