PROTOCOL DEVIATIONS

Only Protocol Deviations that meet the definition of an unanticipated problem should be submitted to the IRB. An Unanticipated Problem includes an incident, experience, or outcome that meets all of the following criteria:

A. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

B. related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

C. 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.

If a protocol deviation meets the above definition then it must be reported to the IRB as an Unanticipated Problem.

*Upstate Medical University uses IRBNet for the electronic administration and management of its IRB. All submissions to the IRB are to be submitted via IRBNet.