

## 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.**