**Guidance on the Use of the Adverse Event Form**

**Western Carolina University IRB**

The **Adverse Event Form** is to be used whenever you encounter a problem or event that is both unanticipated and indicates that the research places subjects or others at a greater risk of harm (including physical, economic, or social harm) than was previously known or recognized.

**Unanticipated** is defined as: unexpected (in terms of nature, severity, or frequency) given:

* The research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and
* The characteristics of the subject population being studied

Examples of problems or events requiring prompt reporting to the IRB include:

* Any problem that is both unanticipated and indicates that the research places subjects or others at increased risk of harm. This would include any new risk.
* Information that indicates an adverse change to the risks or potential benefits of the research. For example:
  + A paper published from another study shows that the risks or potential benefits of the research might be different from those initially presented to the IRB
* Allegation of non-compliance with protocol requirements (including protocol deviations or violations) of IRB policies
* Breach of confidentiality or privacy
* Incarceration of a subject in a protocol not approved to enroll prisoners
* Sponsor imposed suspension for risk
* Complaint of a subject that indicates unexpected risks or cannot be resolved by the research team
* Any departure from the protocol (deviation or violation) that harmed subjects or others; that indicates subjects or others might be at risks of harm; or that compromises the integrity of the research data
* Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application [including a supplementary plan or application], or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects)
* An event that, as dictated by the protocol, requires urgent reporting to the sponsor
* Any change made to the research without prior IRB approval in order to eliminate apparent immediate harm