Guidance on the Use of the Adverse Event Form

The Adverse Event Form is to be used as you conduct your research study whenever you encounter a problem or event that is both unanticipated and indicates that the research places subjects or others are a great 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 indices 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
- Compliant of a subject with the complaint 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.
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