1. **Policy Purpose Statement**

   Federal regulations require that institutions engaging in human subjects research have written procedures to ensure investigators properly report certain events to the Institutional Review Board (IRB). This policy defines those events that require prompt reporting to the Kennesaw State University (KSU) IRB.

2. **Scope**

   This policy applies to all research studies that are overseen by the KSU IRB. For studies involving KSU investigators where KSU has designated another IRB as the IRB of record, investigators must still report to the KSU IRB in accordance with this policy.

3. **Definitions**

   3.1. **Prompt reporting**

3.5. **Serious adverse event**: Any adverse event temporally associated with the individual's participation in research that meets any of the following criteria:

3.5.1. Results in death;

3.5.2. Is life threatening (places the subject at immediate risk of death from the event as it occurs);

3.5.3. Requires inpatient hospitalization or prolongation of existing hospitalization;

3.5.4. Results in a persistent or significant disability/incapacity;

3.5.5. Results in a congenital anomaly/birth defect;

3.5.6. Based upon appropriate medical judgment, may jeopardize the individual's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition;

3.5.7. Results in a breach of confidentiality that is damaging to the participant's rights, employment, financial standing or reputation; or

3.5.8. Causes significant psychological, social, economic, or legal harm to the participant or others.

3.6. **Unexpected adverse event**: Any adverse event occurring in one or more participants when the nature, severity, or frequency is not consistent with either

3.6.1. the known or foreseeable risk described in (a) the protocol-related documents (e.g., the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document) and (b) other relevant sources of information (e.g., product labeling and package inserts);

3.6.2. the expected natural progression of any underlying disease, disorder, or condition of the individuals(s) experiencing the adverse event and the individual's predisposing risk factor profile for the adverse event.

3.7. **Unanticipated adverse device effect (UADE)**: For studies of medical devices, the investigational device exemption regulations define an unanticipated adverse device effect as any serious 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