

**Chamberlain University Institutional Review Board**

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**IORG0008174 / IRB00011037 FWA00021986**

**Unanticipated Problem / Adverse Event Report**

**Reports must be completed, signed by the Principal Investigator, and submitted electronically to the IRB at** **irb@chamberlain.edu** **as soon as possible following a problem or adverse event.**

**An *unanticipated problem*, as described by the Office of Human Research Protections (2007) is an event, experience, or outcome that meets the following:**

1. **Is unexpected in terms of nature, severity, or frequency based on the IRB-approved study protocol and the subject population being studied;**
2. **Is related or possibly related to participation in the research study;**
3. **And suggests that subjects or others are at a greater risk of harm (including physical, psychological, economic, or social) than was previously known or recognized.**

**Unanticipated problems often require notable changes to a study’s protocol and/or informed consent processes.**

**An a*dverse event* is defined as an unfavorable medical occurrence (psychological or physical harm), including a sign, symptom, or disease, temporally associated with participation in the research, whether or not it might be related to a subject’s participation in the research study. If an adverse event meets the three criteria that define an unanticipated problem, the adverse event is also considered an unanticipated problem.**

**Principal Investigator:**

**Title of Study:**

**Date:**

1. **Please describe, in detail, the problem or adverse event. Include non-identifying demographic information of the subject(s) involved.**

1. **Is this an unanticipated problem or adverse event? Please explain.**
2. **If this is an adverse event, was the possibility of this event occurring stated as a potential risk in the informed consent materials?**
3. **Please describe any changes to the study protocol or other corrective actions taken or proposed in response to the unanticipated problem or adverse event.**