

**Chamberlain University Institutional Review Board**

**500 W. Monroe Suite 1300 Chicago, IL 60661Email:** [**irb@chamberlain.edu**](mailto:irb@chamberlain.edu)

**IORG0008174 / IRB00011037 FWA00021986**

**Study Amendment Application Form**

**For submitting Changes to Previously Approved Human Subjects Research Studies**

**Forms must be completed, signed by the Principal Investigator, and submitted electronically to the IRB at** [**irb@chamberlain.edu**](mailto:irb@chamberlain.edu)

***Your amendment application must be approved by the IRB before the implementation of any changes. Failure to receive approval may result in IRB action, including the possibility of closure of the study by the IRB.***

**Study Title:**

1. Is there a new address for correspondence with the principal investigator?

Yes  No If yes, indicate the new address:

1. Original Study Title:

Is this a request to change to the original study title?  Yes  No

If yes, indicate the new title:

1. Is this request due to an unanticipated problem or adverse event?  Yes  No

**(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.)**

If yes, please attach an Unanticipated Problem/ Adverse Event Report Form.

1. Please check one of the following:

The proposed change(s) do not increase risk to study participants.

The proposed change(s) may or will increase risk to study participants.

1. Does the proposed change involve information that might relate to a subject’s willingness to continue to take part in the research?  Yes  No

If yes, please provide an explanation:

1. **REQUIRED**: For each proposed change, describe the currently approved procedures, forms, etc. and then summarize the proposed change, addition, etc. Include a justification for the change request. Attach all revised documents, if appropriate, that reflect the proposed change(s). Please highlight the sections that include the proposed change(s). Add additional sheets if necessary.
2. Currently approved:

Proposed change:

1. Currently approved:

Proposed change:

1. Currently approved:

Proposed change:

*Continue as necessary.*

**Name of Principal Investigator:**

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**Principal Investigator’s Hand or Legal Electronic Signature Date**