

**Chamberlain University Institutional Review Board**

**500 W. Monroe Suite 1300 Chicago, IL 60661**

**Email:** [**irb@chamberlain.edu**](mailto:irb@chamberlain.edu)

**IORG0008174/ IRB00011037 FWA00021986**

**Continuing Review of Study Application Form**

***(Request for Renewal of IRB Approval of Study)***

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

**Unless otherwise noted by the IRB, approved studies which were approved through a full committee review process must be reviewed and granted continued approval at least annually from the date of original approval. Your renewal application must be approved before your current approval expires. If IRB approval has expired, you cannot enroll new subjects and data collection must stop. Studies that have not been re-approved by the expiration date may be closed by the IRB.**

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| **IRB #** | | **(IRB USE - Date Received)** | |
| Study Title: | | | |
| **Principal Investigator:** | | | |
| **Phone:** | **Email:** | | |
| **Please submit the following:**   * A protocol **summary** (*including your hypothesis and methods or procedures, no more than a pagein length*) * A status report on the progress of the research, including:   + a summary of any relevant new literature that might affect a person’s willingness to participate in the study;   + any adverse events or unanticipated problems\*\* involving risks to subjects or others, any withdrawal of subjects from the research, and any complaints about the study since the last IRB review; (Please include a copy of any Unanticipated Problem/ Adverse Event Report form submitted to the IRB);   + amendments or modifications to the research since the last review; (Please include a copy of any Study Amendment Application Forms submitted to the IRB);   + any relevant multi-center trial reports;   + any other relevant new information, especially information about risks associated with the research;   + a copy of the current informed consent document in use for the study;   + a copy of the current study recruitment materials. | | | |
| How many subjects consented, in total to date, during the course of this study? | | |  |
| How many subjects participated, in total to date, during the course of this study? | | |  |
| How many subjects consented in this study to date since the last approval date? | | |  |
| How many subjects participated in this study to date since the last approval date? | | |  |
| If the study was conducted in multiple sites, please list how many subjects consented, in total to date, for each site. (Otherwise, put N/A.) | | |  | |
| If the study was conducted in multiple sites, please list how many subjects participated, in total to date, for each site. (Otherwise, put N/A.) | | |  | |
| If the study was conducted in multiple sites, please list how many subjects consented to date since the last approval date for each site. (Otherwise, put N/A.) | | |  | |
| If the study was conducted in multiple sites, please list how many subjects participated to date since the last approval date for each site. (Otherwise, put N/A.) | | |  | |
| **Hand-signed or legal electronic signature:**        **Date**: | | | | |

**\* Studies that have progressed to the point for which only data analysis is occurring will no longer require continuing review. In these situations, complete the Closure of Study form and submit the completed form to the IRB.**

**\*\*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.**