**Bellarmine University IRB**

**AMENDMENT/TERMINATION/ADVERSE EVENT FORM**

**INSTRUCTIONS**: Submit this completed form and required supporting documents, in a single email to irb@bellarmine.edu. Submitting in multiple emails may delay the review process. *Study Amendments* ***MAY NOT*** *be instituted until written approval from the BU IRB is received****.***

|  |  |
| --- | --- |
| **Project Title and Number:** |  |
| **Principal Investigator:** |  | **Department:** |  |
| **Phone:** |  | **Email:** |  |

**Check here if you are Terminating your study:** [ ]  *If you are terminating your study, skip to question #8.*

**Type of Amendment** *(****Check* ALL *that apply****)***:**

[ ]  **Protocol change** [ ]  **Consent Form change** [ ]  **Study personnel change** [ ]  **Continuation**

[ ]  **Adverse event** *(see #9)*[ ]  **Other:**\_\_\_\_\_

1. **Describe the proposed change(s) and rationale for the change(s).**

*(Do not leave blank.* *You may type in the space provided* *below ****OR SUBMIT*** *a separate document.)*

1. **Study Personnel Change:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Add/Delete** | **Role**(PI, Co-PI, Collaborator, etc.) | **Name** | **Email** | **Department/Affiliation** | **Status\*** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| \*Please indicate faculty, staff, student – graduate (G) or undergraduate (UG), or other (please specify). You may insert additional rows for CoPIs as necessary***OR SUBMIT*** *a separate document.* |
| The following items must be **SUBMITTED** with this form for each new investigator: * (1) Resume/curriculum vitae
* (2) CITI Human Subjects Training Certification (<https://about.citiprogram.org/>); expires after three years
 |

1. **Will the change affect the risk/benefit ratio for the subjects:** [ ]  **Yes**  [ ]  **No** *If “YES”, please explain*: \_\_\_\_ \_

**4. Do you consider these changes to be:** [ ]  **Minor (minimal risk)** [ ]  **Greater than Minimal Risk**

**5. Does the proposed amendment affect the Informed Consent:** [ ]  **Yes**  [ ]  **No**
*(If “YES”, check the appropriate line and attach a copy of the revised Informed Consent, with additions highlighted and deletions marked).*

 [ ]  **The new Informed Consent is in addition to the current one.**  [ ] **The new Informed Consent is to replace the current one.**

**6. Are there any issues of non-compliance to self-report?** \_\_\_\_\_

**7. Has there been any change in sponsorship?** [ ]  **Yes**  [ ]  **No**  *If “YES”, please explain:* \_\_\_\_\_

[ ]  **Check here if you are attaching any documents that deal with the sponsorship change (e.g., notes to or from sponsor, etc.)**

**8.** **STUDY INFORMATION**

**How many subjects, specimens or charts were approved initially for this study?** \_\_\_\_\_ **Enrolled to date:** \_\_\_\_\_

**Total number of subjects, specimens or charts *completed*:** \_\_\_\_\_ **Total number *withdrawn* from study:** \_\_\_\_\_

 **If *withdrawn* from study, please explain:** \_\_\_\_\_

**Total number of subjects, specimens, or charts *currently under study* (intervention/treatment):** \_\_\_\_\_

**Total number of subjects, specimens or charts that are *follow-up ONLY* (post-study data):** \_\_\_\_\_

*(When totaled, the number completed, withdrawn, current and follow-up, should equal the number enrolled.)*

**9. ADVERSE EVENT**

**Side effects, complications or problems encountered during the study, if not previously reported:**

 (*You may type in the space provided below OR SUBMIT a separate document.)*

|  |
| --- |
| **PRINCIPAL INVESTIGATOR SIGNATURE** |
| By providing my name in the box below, I certify that I have read, and I understand Bellarmine University’s policies and procedures governing human subject research as described in Bellarmine IRB Handbook. I will fully comply with those policies and will not conduct any research activities without IRB approval. I further acknowledge my obligation to: (1) obtain written approval of any additional deviations from the originally approved protocol BEFORE making those deviations; and (2) Immediately report all adverse events of the study to the Chairperson of the Institutional Review Board and the Research Sponsor, if applicable. This study will be conducted in a manner consistent with how it has been represented to the IRB and will follow any alterations in the procedures that may result from the IRB review process. |
|  |  |
| **Principal Investigator Signature & Today’s Date** | **CITI Training Completion Date** |

Form Revised August 2022