**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](mailto: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\*** |
|  |  |  |  |  |  |
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|  |  |  |  |  |  |
| \*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