AMENDMENT APPLICATION

SUBMISSION INSTRUCTIONS

Submit the Amendment Application Form and any other supporting documentation to the IRB office electronically (esc-irb@email.laccd.edu). No handwritten forms will be accepted. If changes are being made to the consent form, the application must include copies of the old consent form with tracked changes and clean copies of the new consent form.

LACCD IRB

770 Wilshire Boulevard

Los Angeles, CA 90017

esc-irb@email.laccd.edu

AMENDMENT APPLICATION

PROTOCOL INFORMATION

1. **Level of Review:**

[ ]  Full Committee

 [ ]  Expedited Review - Under Category: Select a Category.

 [ ]  Exempt Review - Under Category: Select a Category.

**Please describe how the amendment qualifies for expedited or exempt review:**

Click here to enter text.

1. **Date Submitted:** Click here to enter a date.
2. **IRB Protocol Identification Number:** XXXX - XX - XXX
3. **Title of Study:** Click here to enter title.
4. **Campus:** Choose LACCD Campus:
5. **Principal Investigator (PI):**

|  |  |
| --- | --- |
| **Name:**Click here to enter text. | **Highest Degree Earned:**Click here to enter text. |
| **Mailing Address:**Click here to enter text.Click here to enter text. | **Phone Number:** (XXX) XXX- XXXX |
| **Extension:** XXXXX |
| **Pager/Cell Phone:**  (XXX) XXX- XXXX |
| **City:** Click here to enter text. | **Fax Number:**  (XXX) XXX- XXXX |
| **State:** State | **Zip:** ZIP\_CODE | **Email:** Email Address |
| **Completion Date of Human Subject Protection Training:** Select Completion Date |

1. **Have there been any changes in investigator or research personnel?**

[ ]  Yes [ ]  No

**If Yes, please specify the addition and/or deletions:**

**List of all Research Personnel:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Completion Date of Human Subject Protection Training:** | **Is this a continuing, new, or removed member of the research team?** |
| Click here to enter name. | MM / DD / YYYY | Choose Status: |
| Click here to enter name. | MM / DD / YYYY | Choose Status: |
| Click here to enter name. | MM / DD / YYYY | Choose Status: |
| Click here to enter name. | MM / DD / YYYY | Choose Status: |
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| Click here to enter name. | MM / DD / YYYY | Choose Status: |
| Click here to enter name. | MM / DD / YYYY | Choose Status: |
| Click here to enter name. | MM / DD / YYYY | Choose Status: |

1. **Date of original IRB approval:** Click here to enter a date.
2. **Why is this amendment being submitted?**

[ ]  In response to a series of adverse events?

[ ]  In response to suggestions from other investigators?

[ ]  To update the consent form?

[ ]  To update survey or interview instruments?

[ ]  Other

**If Other, please describe:**

Click here to enter text.

1. **Type of Changes (Check all that apply):**

[ ]  Changes to protocol only

[ ]  Changes to the consent form only

[ ]  Changes to both the protocol and consent form

[ ]  Change in Funding Source

[ ]  Change in Investigator Personnel

[ ]  Change to (or addition of new) survey or interview instruments

[ ]  Sponsor generated Amendment

[ ]  Investigator generated amendment

[ ]  Other

**If Other, please describe:**

Click here to enter text.

1. **Please provide a summary of all changes:**

Click here to enter text.

1. **Does the amended protocol/consent reflect any change in the risk/benefit relationship?**

[ ]  No [ ]  Yes

**If Yes, please explain:**

Click here to enter text.

1. **Should subjects be notified of any significant new findings?**

[ ]  No [ ]  Yes

**If Yes, please explain:**

Click here to enter text.

PRINCIPAL INVESTIGATOR CERTIFICATION

Signature certifies that the above titled research has been/will be conducted in full compliance with the DHHS/FDA Regulations and IRB requirements/policies governing human subject research. It is understood that any changes in the study/methodology which affect the subjects must be approved by the IRB prior to implementation.

**Signature of PI:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_