# **Instructions**

* Complete each section of this form without changing its format and sign the agreement in section C.
* Obtain the necessary signatures indicating faculty (if necessary) and departmental approval in section D.
* Email the signed application form and all amended accompanying materials to [irb@fxua.edu](mailto:irb@fxua.edu).
* Please note: Applications that are incomplete, unclear, inconsistent, insufficiently proofread for language use and mechanics, and/or different from the provided template will be returned immediately for revisions, which will mean a delay in processing time.

# **Project Information**

## **A1. Project Overview**

|  |  |  |  |
| --- | --- | --- | --- |
| Project Title | Click or tap here to enter text. | | |
| IRB Approval # | Click or tap here to enter text. | | |
| Approval Date | Click or tap here to enter text. | | |
| Project Type | Faculty Research | Student Research *(Specify type and faculty supervisor below)*  Class project *(Provide course #)*: Click or tap here to enter text.  Master’s thesis  Doctoral dissertation  Independent project  Faculty Supervisor: *(Required for any research with a student as the PI)*  Name: Click or tap here to enter text.  Email: Click or tap here to enter text. | Other *(Describe)*: Click or tap here to enter text. |

## **A2. Principal Investigator** *(The PI must also serve as the primary contact for the IRB.)*

|  |  |  |
| --- | --- | --- |
| Name | Click or tap here to enter text. | |
| Professional Title | Click or tap here to enter text. | |
| School/Department | Click or tap here to enter text. | |
| Telephone | Click or tap here to enter text. | |
| Email Address | Click or tap here to enter text. | |
| IRB Training | CITI Social-Behavioral-Educational Basic Course  *Record #*:Click or tap here to enter text.  *Expiration date*: Click or tap here to enter text. | NIH Good Clinical Practice eCourse  *SBM tracking ID #*: Click or tap here to enter text.  *Expiration date*: Click or tap here to enter text. |

# **Proposed Changes**

## **B1. Description of Changes**

*Please provide a detailed description of the changes that you propose implementing, organized systematically to match the organization of your original IRB application.*

Click or tap here to enter text.

## **B2. Rationale for Changes**

*Please explain why these changes are necessary.*

Click or tap here to enter text.

## **B3. Assessment of Risks**

*Will these changes result in additional risks to participants? Please explain.*

Click or tap here to enter text.

## **B4. Minimization of Risks**

*If you answered “yes” to B3, please describe the additional steps that will be taken to minimize any risks to participants.*

Click or tap here to enter text.

# **Investigator Agreement**

*In submitting this Change in Protocol application, I certify the following:*

I will continue to comply with federal, state, and local laws regarding the protection of human participants in research.

I will promptly report to the IRB, in writing, any new findings that develop during this study that may affect the risks and benefits to participants.

I will promptly report to the IRB, in writing, any unexpected or otherwise significant adverse events that occur in the course of this study.

I will maintain records of the data for at least three years following completion of this research.

I will not make any changes to my research protocol unless and until the IRB grants official approval.

I will submit any future changes to the IRB for review and official approval prior to implementation.

Name of PI: Click or tap here to enter text. Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click or tap here to enter text.

# **D. Faculty and/or Departmental Approval**

*I confirm the accuracy of this application. I accept responsibility for the conduct of this research, the protection of human participants, and the maintenance of informed consent documentation as required by the IRB.*

**Faculty Supervisor:** Click or tap here to enter text. Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click or tap here to enter text.

*I have read this application and approve of the procedures that involve human participants.*

**Chair/Department Administrator:** Click or tap here to enter text. Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click or tap here to enter text.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

# **E. For IRB Use Only**

*This application has been reviewed by the IRB, resulting in the following determination:*

Approved; *Category*: Click or tap here to enter text.

Approved; *Subject to Restrictions*: Click or tap here to enter text.

Tabled; *Required Revisions*: Click or tap here to enter text.

Disapproved following Full Review; *Reasons*: Click or tap here to enter text.

**Reviewer:** Click or tap here to enter text. Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click or tap here to enter text.

**IRB Chair:** Click or tap here to enter text. Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click or tap here to enter text.