# **Instructions**

* All unexpected adverse events related or likely related to the research project must be reported to the IRB. To submit an Adverse Event Form, please complete each section of this document without changing its format and sign the agreement in section C.
* Obtain the necessary signatures indicating faculty (if necessary) and departmental acknowledgment in section D.
* Email the signed form and any relevant additional materials to [irb@fxua.edu](mailto:irb@fxua.edu).
* Please note: Forms 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. |

# **Adverse Event or Problem**

## **B1. Type of Event or Problem**

*Please indicate the type of event or problem by checking the applicable statement(s) below:*

Adverse event that was unexpected and related or likely related to the research

Specific protocol-defined event that requires prompt reporting to a sponsor or the IRB

Accidental or unintentional deviation from the IRB-approved protocol that involves or likely involves risks

Information that indicates a change to the risks or potential benefits from the research

Sponsor-imposed suspension due to risk

Breach of confidentiality

Participant complaint that indicates an unanticipated event

Participant complaint that cannot be resolved by the research staff

Incarceration of a participant in a protocol not approved to enroll prisoners

Indication that a participant falls within an elevated-risk group not previously identified

Other: Click or tap here to enter text.

## **B2. Description of the Event or Problem**

|  |  |  |
| --- | --- | --- |
| Description | Click or tap here to enter text. |  |
| Location | Click or tap here to enter text. |  |
| Timing | Date of event: Click or tap here to enter text. | Date of discovery:Click or tap here to enter text. |
| *Have there been any previous occurrences?* ☐ Yes ☐ No  *If yes, please describe:* Click or tap here to enter text. | *Is the event or problem ongoing?* ☐ Yes ☐ No  *If not, describe the outcome:* Click or tap here to enter text. |
| Participants | *Are participants still involved in the study?* ☐ Yes ☐ No | *Is the study permanently closed to new participants?* ☐ Yes ☐ No |

## **B3. Recommendations**

|  |  |  |
| --- | --- | --- |
| Protocol | *Should the protocol be revised?*  ☐ Yes ☐ No  *If yes, please describe how:* Click or tap here to enter text. | |
| Consent Process | *Should the consent document and/or process be revised?* ☐ Yes ☐ No  *If yes, please describe how:* Click or tap here to enter text. | |
| Suspension | *Should the research be suspended?* ☐ Yes ☐ No  *Please explain:* Click or tap here to enter text. | |
| Termination | *Should the research be terminated?* ☐ Yes ☐ No  *Please explain:* Click or tap here to enter text. | |
| Notification | *Should current participants be notified about this problem or event?*  ☐ Yes ☐ No  *If yes, please describe why and how:* Click or tap here to enter text. | *Should past participants be notified about this problem or event?*  ☐ Yes ☐ No  *If yes, please describe why and how:* Click or tap here to enter text. |

# **Investigator Agreement**

*My signature certifies that all necessary information has been assessed and provided to the IRB as promptly as possible.*

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

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

*I confirm the accuracy of this information and accept responsibility for the supervision of this research.*

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

*I have read this information, will provide guidance, and will check to ensure that appropriate actions are taken.*

**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 information has been reviewed by the IRB, resulting in the following recommendations:*

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.