# **Instructions**

* All non-exempt research projects in which data collection lasts for more than one year must undergo an annual review. It is the responsibility of the Principal Investigator to submit this form prior to the end of 11 months from the project’s approved start date or last approved annual review. To submit an Annual Review Form, complete each section of this document without changing its format and sign the agreement in section D.
* Obtain the necessary signatures indicating faculty (if necessary) and departmental acknowledgment in section E.
* Email the signed form 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. |

# **Personnel**

*Identify all personnel who will continue to work on this project, listing the Principal Investigator (PI) first, followed by the Faculty Supervisor, as relevant. Everyone involved in any aspect of the research (including but not limited to recruiting and/or interacting with participants; transcribing, coding, and/or analyzing data; etc.) must submit proof that the required training in the protection of human research participants is still valid.*

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Investigators** | | | | | **Involvement in Research** | | | | **IRB Training** *(Include record # & expiration date)* |
| **#** | **Full Name** | **Title/Status**  *(e.g., Associate Professor, student)* | **Affiliation** *(university & school)* | **Email Address** | **Role** *(e.g., PI, faculty supervisor, additional investigator, research assistant, consultant)* | **Will this person…** | | |
| have contact with human participants? | be involved in the consent process? | have access to private identifiable data? |
| **1** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Principal Investigator | Yes  No | Yes  No | Yes  No | CITI  NIH  Click or tap here to enter text. |
| **2** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Yes  No | Yes  No | Yes  No | CITI  NIH  Click or tap here to enter text. |
| **3** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Yes  No | Yes  No | Yes  No | CITI  NIH  Click or tap here to enter text. |
| **4** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Yes  No | Yes  No | Yes  No | CITI  NIH  Click or tap here to enter text. |

*Include additional rows as needed.*

# **Progress Report**

## **C1. Status of the Project**

Continuing with no changes in protocol or risk

*Expected end date:* Click or tap here to enter text.

Proposed to continue with changes to protocol, pending IRB approval *(\*Must submit a Change in Protocol application form\*)*

Proposed to continue with changes related to adverse events or unexpected risks *(\*Must submit an Adverse Events form\*)*

Completed with no more research to be done

The research will not be conducted

*Please describe any additional information which may be useful to the IRB (e.g., progress made so far, unanticipated problems, complaints received, research activities still to be conducted):*

Click or tap here to enter text.

## **C2. Participants**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Adults** | **Minors** | **Other Vulnerable Populations**  *Please specify:* Click or tap here to enter text. |
| **Total number of participants enrolled to date:** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| # currently participating: | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| # completed: | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| # withdrawn: | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| **Expected number still to be enrolled:** | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

## **C3. Data Security**

|  |  |  |
| --- | --- | --- |
|  | **Electronic Data** | **Physical Data** |
| *Who has access to the data and for what purposes?* | Click or tap here to enter text. | Click or tap here to enter text. |
| *How and where are the data being stored to ensure security?* | Click or tap here to enter text. | Click or tap here to enter text. |
| *How are the links between participants’ identities and the rest of their data being kept private and protected?* | Click or tap here to enter text. | Click or tap here to enter text. |
| *How is participant confidentiality being ensured in reports of the research?* | Click or tap here to enter text. | Click or tap here to enter text. |
| *For how long will the data be retained?* | Click or tap here to enter text. | Click or tap here to enter text. |
| *What will happen to the data and records after the research is complete, and who will be responsible for this?* | Click or tap here to enter text. | Click or tap here to enter text. |

# **Investigator Agreement**

*My signature certifies that the previously approved research protocol has been and will continue to be followed with the approved population(s) of research participants, using the recruitment materials, informed consent process, procedures, data-collection tools, and other materials submitted with the most recently approved application.*

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

# **E. 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 confirm the accuracy of this information and will continue to ensure that the approved protocol is followed, providing guidance as necessary.*

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

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

# **F. 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.