**IRB USE ONLY**

Last name \_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB FORM-05

Revised 12/18/2018

**TEXAS A&M INTERNATIONAL UNIVERSITY**

**IRB Unanticipated/Adverse Event Report**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***Unanticipated or adverse events include matters such as participant complaints, harm (physiological or psychological), theft of data, breaking of confidentiality, among others.***  ***The information provided will be reviewed by the Texas A&M International University Institutional Review Board for compliance with federal regulations and TAMIU’s Federal Wide Assurance document approved by OHRP.*** | | | | | | |
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|  | | | | | | |
| IRB Protocol # | |  | |  | | |
|  |  | | | | | |
| Project Title: |  | | | | | |
|  | | | | |  | |
| Initial Approval Date: | | |  | | Most Recent Approval Date: |  |
|  | | | | |  | |

**INVESTIGATOR INFORMATION**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Principal Investigator Name: | | | |  | | | | | | | | |
|  | | | | | | |  | | | | | |
|  | | | Faculty |  | Staff | |  | | | | | |
|  | | | | | | |  | | | | | |
| Department: | |  | | | | | College: | | |  | | |
|  | | | | | | |  | | | | | |
| Phone: |  | | | | | | E-mail: | |  | | | |
|  | | | | | | |  | | | | | |
| For protocols involving student Co-Investigators: | | | | | | | |  | | | | |
| Is this study part of their Thesis or Dissertation? | | | | | | | |  | | Yes |  | No |
|  | | | | | | |  | | | | | |
| If yes, has it been approved by the committee chair? | | | | | | | |  | | Yes |  | No |
|  | | | | | | |  | | | | | |
| Thesis Committee Chair/Faculty Advisor Name: | | | | | |  | | | | | | |
|  | | | | | | | | | | | | |

**ABOUT THE STUDY**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Funding Status: |  | | | Externally funded | |  | Internally Funded | | |  | Not Funded |
|  |  | | |  | |  |  | | |  |  |
|  |  | | | Grant Application\* | |  | Other | |  | | |
| Funding Agency (if applicable): | |  | | | | | | | | | |
|  | | | | | | | | | | | |
| Does the study involve children? | | | | |  | | | Yes | |  | No |
|  | | | | |  | | |  | |  |  |
| Does the study involve a school/school district? | | | | |  | | | Yes | |  | No |
| If yes, which school district(s)?: | | |  | | | | | | | | |
|  | | | | | | | | | | | |

**ADVERSE EVENT INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
| Is this a follow-up report? | | | |
| Yes | | | |
| No | | | |
|  | | | |
| Date of the Event: |  | Location of the Event: |  |
|  | | | |
| Describe the Adverse Event:  *Use a separate sheet if necessary* | | | |
|  | | | |
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| --- |
| Provide a summary of all the circumstances related to this event. Make sure to include the following information:   1. Who was present during the event 2. Copy/description of all hospitalization/medical treatment and/or follow-up counseling 3. All notifications/correspondence concerning this event 4. Correspondence with the sponsor concerning the event 5. Statement regarding this adverse event in relation to the study at Texas A&M International University |
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| Describe any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated/adverse problem (if appropriate). |
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| --- | --- | --- | --- | --- | --- |
|  | | | | | |
| **Principal Investigator Name:** | |  | | **Date:** |  |
|  | |  |  | |  |
|  | |  |  | |  |
| **Signature:** |  | | | | |
|  |  | | | | |
|  | | | | | |
| **Department Head Name:** | |  | | **Date:** |  |
|  | |  |  | |  |
|  | |  |  | |  |
| **Signature:** |  | | | | |
|  |  | | | | |