**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* |
|  |
|       |

|  |
| --- |
| 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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|       |

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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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|       |

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| **Principal Investigator Name:** |       |  **Date:** |       |
|  |  |  |  |
|  |  |  |  |
| **Signature:** |  |
|  |  |
|  |
| **Department Head Name:** |       |  **Date:** |       |
|  |  |  |  |
|  |  |  |  |
| **Signature:** |  |
|  |  |