**Texas Woman’s University**

**Institutional Review Board**

**Incident Report Form Instructions**

TWU investigators conducting research with human participants are responsible for reporting all incidents that may be considered adverse events, unanticipated problems, or serious or continuing noncompliance.

* Incidents must be reported verbally or in writing to the IRB Office (940-898-3378 for Denton or Dallas and 713-794-2480 for Houston or email [irb@twu.edu](mailto:irb@twu.edu)) within two (2) working days of the occurrence.
* A completed IRB Incident Report Form must be submitted to the IRB within five (5) working days of the occurrence.

**Definitions**

***Adverse event:*** any untoward or unfavorable occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. Adverse events encompass both physical and psychological harms.

***Unanticipated problem:*** any incident, experience, adverse event, or outcome that meets all of the following criteria:

* 1. Unexpected given the described procedures, informed consent, and population characteristics
  2. Related or possibly related to participation in the research
  3. Suggests that participants are placed at greater risk than previously known

Adverse events and unanticipated problems are not mutually exclusive. An adverse event is not necessarily an unanticipated problem and visa versa. The IRB makes the final determination on categories of incidents.

***Noncompliance:*** failure to comply with federal or state regulations or TWU policies governing research with human participants or the requirements or determinations of the IRB. The IRB will evaluate the degree of noncompliance on a case-by-case basis.

1. **Project Information –** Complete all applicable sections
2. **Incident –** Complete all applicable sections
   1. **Detailed description of the incident**: Include location, impact of incident on subject(s), how the incident was brought to the attention of the research team, number of participants effected/involved.
   2. **Is the incident unexpected given the described procedures, informed consent, and population characteristics?** Review your protocols, consent documents and participant description.
   3. **Is the incident related or possibly related to participation in the research?** Would the incident have occurred if effected individuals were not participating in the study?
   4. **Does the incident place participants at greater risk than previously known?** Does the incident suggest that the research places participants or others at a greater risk of physical or psychological harm than was previously recognized?
3. **Corrective actions** – Complete all sections. Corrective actions may include: changes to the protocol; modification of inclusion/exclusion criteria; suspension of enrollment; modification of informed consent documents; informing current and part participants of newly recognized risk(s).

**Note**: Any proposed changes to a research study must be reviewed and approved by the IRB before being implemented, except when necessary to eliminate apparent immediate hazards to subjects.

**Notifications by the IRB**

The IRB will notify department administrator(s) or other entities as necessary following review of incident reports.

Information on adverse and unanticipated problems can be found on the Office for Human Research Protections (OHRP) website at <http://www.hhs.gov/ohrp/policy/advevntguid.html>.

Contact the IRB Office in the Office of Research and Sponsored Programs (940-898-3378) with questions.

**TWU Institutional Review Board**

**Incident Report Form**

**I. Project Information**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Principal Investigator: | | |  | |
| Project Title: | | |  | |
| Project Period | | | From: | To: |
| Funding Agency: |  | | | |
| Funding Agency Project Number | |  | |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date of Event: |  | Date of verbal report to IRB |  | Date of Report |  |

**II. Incident**

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| --- |
| A. Detailed description of the incident: |
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| --- | --- | --- |
| B. Is the incident unexpected given the described procedures, informed consent, and population characteristics? | Yes | No |
| Explain. | | |
|  | | |

|  |  |  |
| --- | --- | --- |
| C. Is the incident related or possibly related to participation in the research? | Yes | No |
| Explain. | | |
|  | | |

|  |  |  |
| --- | --- | --- |
| D. Does the incident place participants at greater risk than previously known? | Yes | No |
| Explain | | |
|  | | |

**III. Corrective Actions**

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| --- |
| Describe actions to correct problem and prevent recurrence |
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| Attach copies of all revisions, notifications and correspondence related to correction of the problem |

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| Principal Investigator Signature | Date |

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| IRB Actions |
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Signature, IRB Chair Date