**THE UNIVERSITY OF TEXAS AT TYLER**

**INSTITUTIONAL REVIEW BOARD (IRB)**

 **IRB RESEARCH MISCONDUCT AND NON-COMPLIANCE REVIEW FORM**

This form is to be completed by the IRB Chairperson and the ad hoc investigative committee in conjunction with the UT Tyler **Procedures for Investigating and Reporting Incidents of Research Misconduct and Non-Compliance** (refer to the University of Texas at Tyler Institutional Review Board (IRB) Handbook). Upon completion, this form is to be submitted to the UT Tyler Office of Sponsored Research, Vice President for Research and Federal Relations.

Date: Click here to enter text.

Reviewer: Click here to enter text.

Study: Click here to enter text.

Principal Investigator: Click here to enter text.

Level of Study Risk: [ ]  Minimal [ ]  Greater than Minimal

Category of Review: [ ]  Exempt [ ]  Expedited [ ]  Full Board

Type of Misconduct: [ ]  Fabrication [ ]  Falsification [ ]  Plagiarism

Type of Non-Compliance: [ ]  General [ ]  Serious [ ]  Continuing

Summary/General Comments:

1. *Please indicate the nature of the non-compliance*

[ ]  Deviated from approved IRB protocol

 [ ]  Failed to follow IRB procedures

 [ ]  Failed to protect participants' rights

 [ ]  Other: Click here to enter text.

2. *Please list non-compliance history for PI, Co-PI, and faculty sponsors.*

 Click here to enter text.

3. *Please list PI, Co-PI, and faculty sponsor type and dates of human subjects training.*

 Click here to enter text.

4. How was this event reported to the IRB? Click here to enter text.

5. What steps if any did the investigator take to rectify the non-compliance?

 Click here to enter text.

6. Implications for risk to participants*:*  Click here to enter text.

7. Implications for informed consent process*:*  Click here to enter text.

8. Implications for the training of researchers*:*  Click here to enter text.

9. Were there any injuries/adverse events/unanticipated events?

 Yes [ ] No [ ]

10. If so, please list: Click here to enter text.

11. Please list recommendations of ad hoc investigative committee for how to resolve this non-compliance case:

Click here to enter text.

12. Please list final recommendations of IRB to be forwarded to the Office of Sponsored Research:

 Click here to enter text.