

**Tarrant County College District
Institutional Review Board
Adverse Event Report**

Date:

Principal Investigator:

Study Title:

Adverse Event: Describe the adverse event associated with this research study.

Ethical Concerns: Describe any ethical concerns regarding this research study.

Principal Investigator's Signature:

Date:

Complete the following regarding the unanticipated event:

1. How many subjects were involved in the adverse event?
2. Has any similar adverse event occurred in this study? If yes, describe:
3. Has the study been discontinued due to the adverse event? If yes, why?
4. In your opinion, in what manner was the adverse effect related to the research study:

Unrelated

Related

Unknown
5. Describe how you propose to protect other participants from exposure to this harm.

Email forms and supporting documentation to: irb.irpe2@tccd.edu.