**Institutional**

**Review**

**Board**

**Mercy College of Health Sciences: Institutional Review Board (IRB)**

**Unanticipated Problem/Adverse Event Reporting**

\*\*Return this completed form promptly to **IRB@mchs.edu**.

Principal Investigator:

Email:

Phone Number:

Study Title:

IRB Reference #:

Study Site:

Co-Investigator, if applicable:

Date and time of the Unanticipated Problem or Adverse Event:

Describe the Unanticipated Problem or Adverse Event (in detail). Refer to the OHRP Website: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q1> for guidance.

Explain how you determined that the event, incident, experience, or outcome represents an unanticipated problem or adverse event.

Describe any changes to the study protocol, and/or other corrective actions taken or proposed as a result of the unanticipated problem or adverse event.

For questions, contact IRB@mchs.edu.

Updated: 4.13.2021