Office of Research Integrity
Institutional Review Board (IRB)
2000 University Avenue
Muncie, IN 47306-0155
Phone: 765-285-5052

BALL STATE UNIVERSITY

IRB RESEARCH RELATED INCIDENT REPORT(v.4.0)

A. Study and PI Information			
IRB Project/Protocol Number	Error! Bookmark not defined.		
Date	Click or tap to enter a date.		
Principal Investigator (PI)		**Email**	
Department/School			
Protocol Title			
Faculty Advisor (If PI is a student)			

B. Sponsor/Funding Agency

Please fill out this section, if applicable.
Sponsor/Funding Agency:
Have you communicated with SPA regarding this incident? ☐ Yes ☐ No
Have the Sponsor/Funding Agency been notified of this event? ☐ Yes ☐ No

C. Incident Information

1. Type of Incident Please check all that apply.

The incident(s) must be reported to the IRB within 5 business days unless it is a Serious Adverse Event which must be reported within 24 hours after the incident.

- ☐ Breach of Privacy
- ☐ Breach of Data or Research Security
- ☐ Complaint Registered by Participant or Study Site
- ☐ Economic/ Social Harm
- ☐ Medical (Emergency, Hospitalization, Disability, Incapacitated, etc.)
- ☐ Possible FERPA Violation
- ☐ Possible HIPAA Violation
- ☐ Protocol Deviation
- ☐ Psychological Harm or Injury
- ☐ Other (Explain below):

2. Any Adverse Event/ or Serious Adverse Event?

☐ Adverse Event (AE) ☐ Serious Adverse Event (SAE) ☐ Not Applicable

Please visit the following link for more information about AE/SAE:
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q2

3. Start date	Click or tap to enter a date.	**End date**	Click or tap to enter a date.
4. Report Type	☐ initial ☐ follow-up (from previous reported event)		

5. **Was(were) any research team member(s) listed in the key personnel involved in this incident?**

☐ Yes ☐ No

If yes, please list the name(s).

(name, affiliation, and role)

6. **Was(were) any participant(s) involved in the incident?**

☐ Yes, directly involved
☐ Yes, indirectly involved
☐ No

a. If participant(s) was(were) directly involved in the incident, please provide their information, if available.

(name, age, and contact information, if available)

b. Please check all that apply.

☐ The participant(s) completed the study
☐ The participant(s) continued to participate in the study.
☐ The PI withdrew the participant(s) from further participation.
☐ The participant(s) withdraw from the study.
☐ Other (explain):

7. **Please provide a brief description of the event.**

8. **Please explain what corrective actions and preventative measures have been taken as a result of the incident (including revisions to the protocol, informed consent, and any other study documents).**

D. Status of Research

1. **What is the status of the project?**

☐ Continue as planned without any modifications
☐ Continue with changes
☐ Suspend new participant enrollment until further assessment is complete
☐ Terminate the study (all participants have been removed from the study and no data collection will occur

2. **Is there any addition information IRB should know?**

Submission for this IRB Research Related Incident Report Form must be electronically signed in IRBNet by the Principal Investigator (and Faculty Advisor, if student is PI). Your electronic signature indicates your certification that the information provided in this document is accurate and current.