



**SOUTHWESTERN COMMUNITY COLLEGE DISTRICT
 INSTITUTIONAL RESEARCH REVIEW BOARD
 Reporting Adverse Events/ Unanticipated Problems**

Reporting Adverse/ Unanticipated Problems	
In the space provided include all individuals who will interact or intervene with human subjects or their private identifiable information.	
Date of Submission	
Project Title	
Principle Investigator	
Department	
Address	
Telephone Number	
Email Address	
Date of Adverse Event/ Unanticipated Problem	
1. Was the event unexpected in terms of nature, severity, or frequency? Yes <input type="checkbox"/> No <input type="checkbox"/>	
2. Was the event related or possibly related to participation in the research? Yes <input type="checkbox"/> No <input type="checkbox"/>	
3. Does the event suggest that the research places participants or others at a greater risk of harm than was previously known or recognized? Yes <input type="checkbox"/> No <input type="checkbox"/>	
4. Please describe the event. Attach additional pages or supplementary information if necessary. Include date(s) of the event, date of discovery, describe the harm or potential harm that occurred, if the incident is resolved, and if the participant(s) remain in the study.	
5. What action was taken with the study as a result of the event? (check all that apply) <input type="checkbox"/> Revision of protocol to eliminate apparent immediate hazards to participants <input type="checkbox"/> Modification of inclusion or exclusion criteria to mitigate newly identified risks <input type="checkbox"/> Implementation of additional procedures for monitoring participants <input type="checkbox"/> Modification of consent documents to include a description of newly recognized risks <input type="checkbox"/> Suspension of enrollment of new participants <input type="checkbox"/> Notification of currently enrolled participants <input type="checkbox"/> Suspension of research procedures in currently enrolled participants <input type="checkbox"/> Provision of additional information about newly recognized risks to previously enrolled participants <input type="checkbox"/> Other, explain Click or tap here to enter text. <input type="checkbox"/> No action taken, explain Click or tap here to enter text.	
I agree to follow all requirements and to adhere to the guidelines outlined in Southwestern Community College District's IRRB Policy and Procedure Summary.	
Print: _____	Signature: _____
Date: _____	