RHODE ISLAND COLLEGE
INSTITUTIONAL REVIEW BOARD
Unanticipated Problems / Adverse Events Report

All unanticipated problems/adverse events must be reported within 48 hours of occurrence. This form and any supporting documents must be sent to IRB@ric.edu.

IRB Project #:	
Expiration date:	
Project title:	
Principal Investigator Name:	
email:	
phone:	
CITI ID number	
CITI completion date	

Does the noncompliance being reported involve any other collaborating organizations outside of Rhode Island College?

Yes ☐ No ☐

If yes, please list all collaborating organizations: _____

Is there more than one event to report at this time? Yes ☐ No ☐

Provide the following information for **each** unanticipated problem/event that is serious and possibly related to the research procedures. Send additional pages if necessary.

Date of event:	
Date of this report:	
Describe problems/event, including where it occurred:	

How is the problem/event related to the research?

Possibly related ☐ Probably related ☐ Definitely related ☐

Does this problem/event alter risk to past, present or future subjects?

Yes ☐ No ☐ Don't know (insufficient information) ☐

If yes, please describe how _____

Based on your judgment, should this problem/event be added to the consent form as a potential risk?

Yes		Provide revised consent form with changes highlighted
No		Explain why not:

Based on your analysis of this problem/event:

Should currently enrolled participants be notified?	**Yes**		No	
Should participants who have completed the study be notified?	**Yes**		No	
Explain:				

Statement of Responsibility

I understand that typing my name below serves as an electronic signature. I confirm that my CITI training is current (within the last 5 years). I understand the requirements for the ethical conduct of research, and that I am accepting the responsibilities associated with this research project. All of the information reported here is accurate, and no relevant information has been omitted.

Responsible Investigator Signature:		Date:	

For office use only:
Primary reviewer's comments
Secondary reviewer's comments
IRB Chair's comments