



Unanticipated Event Reporting Form – DEC Approved Research

**Please submit completed form to DEC Chair*
(DEC Chair - Please send form to UHREB)*

Investigator and Protocol Information

Applicant	
Date of Event Occurrence	
Telephone Number	
Email	
Protocol Title	
Protocol Number	
Supervisor	
Department	

Event Details

Definitions: As per Guidance Document 7, an **adverse event** is a situation that occurs in the course of the research that has undesirable consequences for study participants and has potential to affect the risk level of the protocol (e.g., breach of privacy of information, negative physical or psychological effects, harms to participants, under taking a study without an assigned consent form, the inclusion of vulnerable populations not detailed in the protocol, etc.). An **unanticipated event** doesn't affect the level of risk to participants and includes such things as higher levels of participant interest than the researcher had planned, unintended errors in communication of information to participants, or a third party sharing the protocol on social media without prior permission from the researcher. Further, **protocol deviations** include any such activities that deviate from the protocol and may therefore require an amendment. Protocol deviations/amendments must be submitted in the post-approval activity section of WebGrants.

*If you are reporting an adverse event, please **SUSPEND** any active research activities until the event can be reviewed.*

If you are reporting an unanticipated issue that is likely to be a permanent protocol deviation, please also submit an amendment form (SOP 404.5.3.2).

1. Do you consider this an Adverse Event or Unanticipated Event?

2. Description of Event

3. Describe whether and how this event affected, or had the potential to affect, the risk level of the protocol or risk to participants.

4. How many participants were affected and/or recruited?

5. What progress have you made on the project?

6. Were any corrective measures taken? If yes, what were those measures?

7. Attachments (Please attach any related study materials – i.e. recruitment materials, surveys, original approved application)

List of items attached:

8. Any other applicable information (Example: How will the event affect the pedagogical aims, course delivery, and/or evaluation?)