OCREAC

Ottawa-Carleton Research and Evaluation Advisory Committee

RESEARCH and/or EVALUATION

UNANTICIPATED ISSUES/ADVERSE EVENTS FORM

for the

Ottawa-Carleton District School Board

133 Greenbank Road ▪ Nepean ▪ Ontario ▪ K2H 6L3

Ottawa Catholic School Board

570 Hunt Club West ▪ Nepean ▪ Ontario ▪ K2G 3R4

UNANTICIPATED ISSUES/ADVERSE EVENTS FORM

Unanticipated issues and adverse events related to OCREAC approved research studies must be reported to the OCREAC Chair *immediately* by submitting this form.

This form is to be used to report:

Adverse Events: Any unfavourable or unintended occurrence in the health (mental, emotional or psychological) or well-being of a research participant. Adverse events may be *expected* in any study where *potential risks* (even minimal) have been identified (i.e., studies with minimal risk or more). Researchers should already have safeguards in place to deal with such events (e.g., resources, information, procedures).

Unanticipated Issues: Any incident, experience, or outcome that is:

- Unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the application documents (e.g. the OCREAC-approved research protocol, informed consent) and/or the characteristics of the research participant population being studied
- Related or possibly related to participation in the research (the event, experience, or outcome may have been caused by the study procedures or methods)
- Indicative that the research places research participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized
- May have immediate or potential implications for current or future participants

OCREAC recognizes that it may be difficult to determine whether a particular incident, experience, or outcome is unexpected and whether it is related or possibly related to participation in the research. An incident, experience, or outcome that meets the criteria for an **unanticipated issue** will usually warrant consideration of changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of participants or others. Examples of corrective actions or changes that might need to be considered in response to an unanticipated issue include:

- Changes to the research protocol initiated by the investigator to eliminate apparent risks to participants;
- Modification of inclusion or exclusion criteria to mitigate the newly identified risks;
- Implementation of additional procedures for monitoring participants;
- Suspension of recruitment of new participants;
- Suspension of research procedures in current participants;
- Modification of informed consent documents to include a description of newly recognized risks; and
- Provision of additional information about newly recognized risks to previously enrolled participants.

Complete the online form here

If you have any questions regarding the completion of this electronic form, please contact: ocreac@ocdsb.ca

PART A: APPLICANT INFORMATION

Name of Principal Investigator:

Address:

Position held:

Institution:

e-mail:

Telephone:

PART B: PROJECT INFORMATION

Title of Research Project:

PART C: DESCRIPTION OF ISSUE OR ADVERSE EVENT

A. Type of event: **Unanticipated Issue** ☐
Adverse Event ☐

B. Description of the issue(s) or adverse event(s) encountered during the study.

Date of event:

Date research team was made aware of event:

Location: **School site or board property** ☐
Off-site (not on school or board property) ☐

Detailed description of event:

C. Assessment of Issue or Adverse Event

		Yes	No	
a)	Is this adverse event/unanticipated problem **unexpected** (in that it was not identified as a potential risk in your initial application)?	☐	☐	
b)	Is this adverse event/unanticipated problem related or possibly **related to the research procedures or protocol**?	☐	☐	
c)	Does this adverse event/unanticipated problem require **change(s) to the study protocol**?	☐	☐	If yes, please complete **Part E** of the **Renewal, Extension or Modification Form**, and submit copies of revised documents.
d)	Does this adverse event/unanticipated problem require **change(s) to information or consent form(s)**?	☐	☐	
e)	Does this adverse event/unanticipated problem require **notification to research participants** (past or present)?	☐	☐	If no, please explain:

D. Has anyone been notified of this event?

Yes ☐ Who and when?
No ☐ Why not? Please explain.

E. What action (if any) has been taken, or will be taken, to respond to this event?

PART E: SIGNATURES

Signature of Principal Investigator:

Date _____ **Principal Investigator Signature** _____

If the Principal Investigator is a student, this form must be countersigned by the student's staff advisor.

Date _____ **Faculty Signature** _____