

Appendix 6: Ontario Health Study – Unanticipated Event/Significant Change Report

This *Unanticipated Event/Significant Change Report* must be submitted to the Data Access Committee for the occurrence of Unanticipated Events and/or Significant Changes during an approved research project that may have an impact on the OHS data, OHS Biosamples, Derived Data, and/or the ability of the Approved User to achieve his research goals.

Notification of compromised data or material security, integrity or confidentiality, or a breach of ethics must be reported at the first reasonable opportunity by telephone to OHS DAC, followed by this written notice report within 48 hours of the event.

File number (provided in your original approval letter): _____

Original title and summary of the main research project:

1. Name of applicant including affiliation and contact details.

Name:
Title:
Position:
Affiliation:
Institutional E-mail Address:
Mailing Address:

2. Name of the authorized institutional representative, including affiliation and contact details.

Name:
Title:
Position:
Affiliation:
Institutional E-mail Address:
Mailing Address:

3. Title of Project

4. Description of the Unanticipated Event/Significant Change

a) Date of the event: _____

b) Requesting additional variables for the same participants for a previously approved *Data and Biosample Access Application*.

c) Description of the unanticipated event/significant change.

d) Has the Research Ethics Board or a comparable decisional committee been notified?

e) What action (if any) has been taken, or will be taken, by the Approved User?

Principal Applicant:

Name _____

Position _____

Signature _____

Date _____

Authorized Institutional Representative of the host institution:

Name _____

Position _____

Signature _____

Date _____

Please e-mail a PDF of the signed *Unanticipated Event/Significant Change Report* to access@ontariohealthstudy.ca.