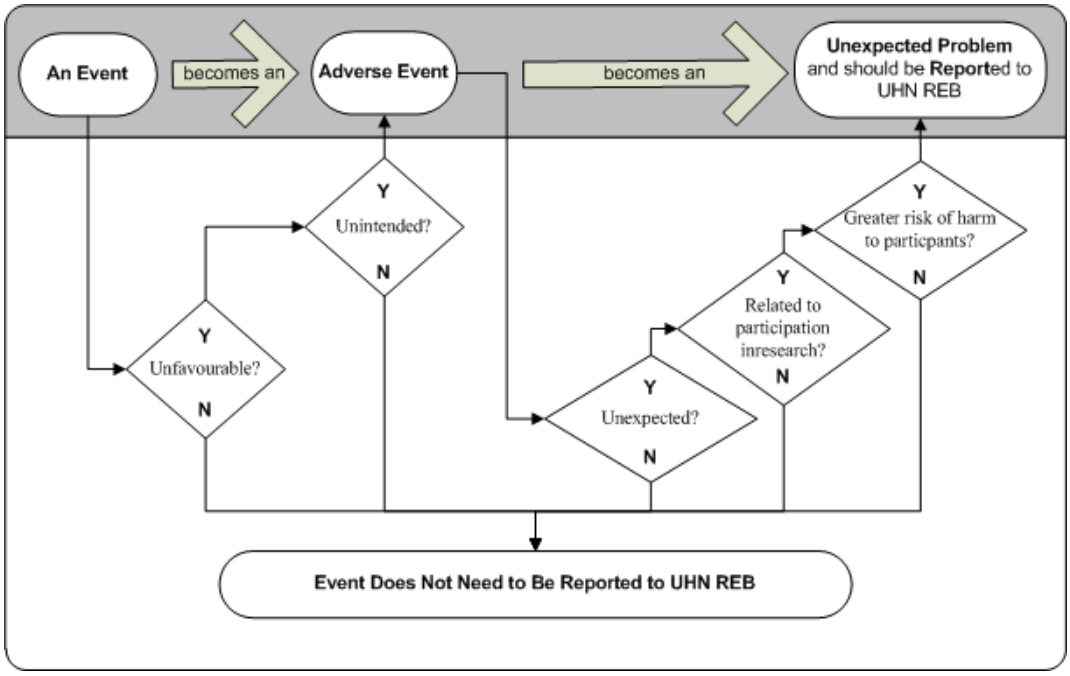
Identifying and Reporting an Unanticipated Problem

The UHN REB has adopted the Canadian Association of Research Ethics Boards' "Guidance on Reporting of Unanticipated Problems including Adverse Events to Research Ethics Boards in Canada" (July 2010).

An **Event** is considered an **Adverse Event** (AE) when it results in any unfavourable and unintended sign (including, for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of an investigational product, whether or not it is known to be related to the investigational product.

An **Adverse Event** is considered an **Unanticipated Problem** and should be reported to UHN REB via an **Unanticipated Problem Report** (UPR) when ALL THREE conditions below are met:

1) The Adverse Event is unexpected (in terms of nature, severity, or frequency) according to:
    a. the research procedures that are described in the protocol-related documents and/or
    b. the characteristics of the research participant population being studied.
2) The Adverse Event is related to participation in the research or that there is a reasonable possibility that the Adverse Event *may* have been caused by the investigational product(s) or procedure(s) involved in the research
3) The Adverse Event suggests 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.



To report an Unanticipated Event at UHN, please do so via CAPCR within 15 calendar days of the Principal Investigator becoming aware of the event. When the Unanticipated Event is fatal or life-threatening it should be reported to the UHN REB within 7 calendar days.

NOTE: Related Periodic Safety Reports, DSMB reports, Protocol Deviations/Violations, and other safety reports should be submitted as supporting documentation to an **Unanticipated Problem Report** as per above criteria.