WINDSOR REGIONAL HOSPITAL
OUTSTANDING CARE – NO EXCEPTIONS!

RESEARCH ETHICS BOARD

REPORTING OF LOCAL and NON-LOCAL ADVERSE EVENTS GUIDELINES

DEFINITIONS

- **Adverse Event (AE):** Any untoward medical occurrence in a research participant administered a drug/intervention that does not necessarily have to have a causal relationship with the drug/intervention.

- **Serious Adverse Event (SAE):** Is any adverse occurrence or response to a drug/intervention, whether expected or not, that:
  - Results in death
  - Is life-threatening
  - Requires inpatient hospitalization or prolongation of existing hospitalization
  - Results in persistent or significant disability/incapacity
  - Results in a congenital anomaly/birth defect
  - Based on appropriate medical judgement, is an important medical event that may jeopardize the health of the research participant or may require medical intervention to prevent one of the outcomes listed above

REPORTING LOCAL SERIOUS ADVERSE EVENTS

- Use the **Local Serious Adverse Event Report** form.

- All local SAEs, whether expected or not, must be reported promptly to the WRH REB if, in the opinion of the investigator, the event may be related to the study drug/intervention.

- Prompt reporting of all locally occurring SAEs, drug-related or other, require reporting as follows:

  - If the SAE is neither fatal nor life-threatening, report **within 15 days** after becoming aware of the information;
  - If the SAE is fatal or life threatening, report **within 48 hours** after becoming aware of the information.

- The reporting of SAEs **may not** be deferred to the Annual Progress Report.

- Local SAEs must be reported by the Local Principal Investigator to the study Sponsor or appropriate federal government agencies (e.g. Health Canada) and any other REBs who have reviewed the study or are affiliated with the researchers. **Note:** the study Sponsor is legally required to report serious unexpected adverse drug reactions to Health Canada either within 15 days (not fatal or life-threatening) or within 7 days (fatal or life threatening) of becoming aware of the information.

- If the local site is part of a multi-centre study, the Local Principal Investigator must also append the most recent **Data Safety Monitoring Board (DSMB) or Sponsor-generated Safety Report** summarizing SAEs to date and any implications for the risk-benefit ratio, as described below.

REPORTING NON-LOCAL SERIOUS ADVERSE EVENTS

If the local site is part of a multi-centre study, the Local Principal Investigator is responsible for providing regular (2-3 times per year) DSMB or Sponsor-generated Safety Reports to the WRH REB, as described below.

DATA SAFETY MONITORING BOARD (DSMB) AND SPONSOR-GENERATED SAFETY REPORTS

- All DSMB Reports must be forwarded as soon as they are available and must be accompanied by a letter from the Locally Responsible Investigator indicating that they accept the findings and recommendations of the DSMB.

- Sponsor-generated reports must contain the following information:

    - Total number of participants
    - Total number of serious adverse events
    - Total number of serious adverse events likely related to the study drug/intervention
    - Whether the study should continue

- The Sponsor-generated reports must be accompanied by a Cover Letter from the Local Principal Investigator indicating their assessment of the seriousness and causality of the side effects and whether in their opinion they alter the risk/benefit ratio and/or require changes to the Information/Consent documents, Protocol, or other study documents. No WRH REB form required.

WRH REB LOCAL SERIOUS ADVERSE EVENT REPORT FORM

- All reports must be submitted in a timely manner. Local site occurrence must be reported within 5 days.

- Use one (1) form for each local serious adverse event (Note: non-local serious adverse events should be reported separately).

- Email one (1) copy of the Local Serious Adverse Event Report form and any supporting documents to the WRH Research Ethics Board at research.ethics@wrh.on.ca

- If Local Principal Investigator causal relationship differs from Sponsor, the Local Investigator is requested to comment in order to help clarify any contrary opinion to the responses received from Sponsor and Local Investigator.

- If both Local Principal Investigator and the Sponsor state “Unknown” as to causal relationship to study drug, the Local Investigator must provide comment.

References

1. https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/international-conference-harmonisation/efficacy/clinical-safety-data-management-definitions-standards-expedited-reporting-topic.html

2. https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/post-authorization-requirements.html#adr