WINDSOR REGIONAL HOSPITAL
OUTSTANDING CARE – NO EXCEPTIONS!

Research Ethics Board

Serious Adverse Event Reporting:

A **Serious Adverse Event (SAE)** is any adverse occurrence or response to a drug/intervention, whether expected or not, that requires in-patient hospitalization or prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity that is life threatening or that results in death.

Local Serious Adverse Events:

- Use the Local Serious Adverse Event Report form.

- All local Serious Adverse Events, whether expected or not, must be reported promptly to the Research Ethics Board, if in the opinion of the investigator the event may be related to the study drug / intervention.

- Prompt reporting of all locally occurring serious adverse events, drug-related or other, which requires reporting as follows:

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

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

    - In addition, local SAEs must be reported by the Locally Responsible Investigator to the study Sponsor or appropriate federal government agencies (e.g. Health Canada).
    - If the local site is part of a multi-centre study, the Locally Responsible Investigator must also append the most recent *Data Safety Monitoring Board (DSMB) or a Sponsor-generated Safety Report* summarizing Serious Adverse Events to-date and any implications for the risk/benefit ratio, as described below.

Non-local Serious Adverse Events:

If the local site is part of a multi-centre study, the Locally Responsible Investigator is responsible for providing regular (2 to 3 times per year) **DSMB or Sponsor-generated Safety Reports** to the REB Office, 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 s/he accepts 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 report must be accompanied by a Cover Letter from the Locally Responsible Investigator indicating his/her assessment of the seriousness and causality of the side effects and whether in his/her opinion they alter the risk/benefit ratio and/or require changes to the Information/Consent documents, Protocol, or other study documents.

IND (SAE) Reports & Local Serious Adverse Event Reporting

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

- Submit **(4) copies** of reports with REB summary log form signed by Investigator attached to front of each set.

- Fill each log as much as possible if you have a number of reports for one study.

- Multiple events in one report are to be noted separately on log.

- List in sequential order if possible / applicable (e.g. – same report # - Initial; Follow-up)

- Individual Reports that are more than one page are to be stapled together.

- Use Relationship to Study Drug Legend on Report Log.

- If Reporting Investigator casual 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 Reporting Investigator.

- If both reporting Investigator and the Sponsor state Unknown as to casual relationship to study drug, the Local Investigator is requested to comment.