

# Memo

## Submission of Non-Local (External) Adverse Events

In accordance with the Canadian Association of Research Ethics Boards Guidance on Reporting of Unanticipated Problems including Adverse Events to Research Ethics Boards in Canada (2010) and RVH REB SOP 404, the REB will only accept non-local adverse event reports if the event is deemed to be an unanticipated problem AND requires a change to the protocol and/or informed consent form and/or requires immediate notification to participants for safety reasons. If the above criteria are met, the submitted report must contain sufficient information to put the event into context. Line listings alone are not acceptable unless they include an assessment of the evolving safety profile of the investigational product. This does not change the sponsor reporting of individual reports to the Principle Investigator(s).

### *SOP 404.003 – Ongoing REB Review Activities*

*5.2.3 Non-Local (External) Adverse Events: Upon receipt of an external adverse event (EAE) or a periodic safety update or safety summary report, the Researcher must determine if it meets the REB reporting criteria:*

- *Non-local adverse event reports are reportable to the REB, if in the opinion of the Researcher, it meets the definition of an unanticipated problem AND requires a change to the research and/or informed consent form and/or requires immediate notification to participants for safety reasons,*
- *The report submitted to the REB must include **all** of the following information:*
  - *The description of the serious and unexpected event(s),*
  - *All previous safety reports concerning similar adverse events,*
  - *An analysis of the significance of the current adverse event(s) in light of the previous reports, **and***
  - *The proposed research changes, informed consent form changes or other corrective actions to be taken by the sponsor in response to the event(s),*
- *The individual AE reports or periodic safety updates or safety summary reports that meet the reporting criteria must be submitted to the REB in a timely manner*