



# Ontario Shores

## Centre for Mental Health Sciences

14 December 2011

**To All Principal Investigators Submitting Clinical Trials to Ontario Shores REB:**

**Criteria for Reporting External/Local Serious Adverse Events:**

Ontario Shores REB has recently changed and updated the requirements for reporting external serious adverse events (External SAEs) in the case of multi-centre clinical trials. The intent of this change is to reduce the burden of SAE reporting to the REB with an emphasis on local events while leaving global reporting in a summarized form to the Sponsor.

As of December 7<sup>th</sup>, 2011, Ontario Shores REB has unanimously approved that for multi-centre studies, principal investigators (PIs) are no longer required to report individual external adverse events unless they are ***unanticipated problems*** as defined by ***CAREB Adverse Events Guidance (Final), July 2010*** document. Instead, PI should provide a periodic consolidated 3-monthly safety updates report prepared by the sponsor to the REB. Individual isolated external adverse events should only be reported to the REB if they are unanticipated problems and the report includes ***all of the following information:***

- the event described is both serious and unexpected,
- the report identifies all previous safety reports concerning similar adverse experiences,
- the report analyzes the significance of the current adverse experience in light of the previous reports, **and**
- the report outlines any proposed protocol changes, informed consent form changes or other corrective actions to be taken by the sponsor in response to the unanticipated problem

Reports not meeting these requirements should be returned to the submitter with a description of Ontario Shores REB reporting requirements.

Ontario Shores REB office will acknowledge periodic 3-monthly safety update reports or those individual isolated external adverse events which meet the above mentioned criteria.

However, for **local serious adverse event(s)**, each incident should be reported to Ontario Shores' REB along with the more detailed report of the event(s) provided to the external sponsor (if any). Ontario Shores' REB office will determine if further review is required or not. The REB will acknowledge receipt of this SAE submission.

**Reporting Timeline for *local serious adverse events:***

48 hours for Fatal/Life Threatening SAEs

10 business days for Non-Fatal SAEs