

# Memo

To: Ontario Centres Using OCREB

From: Ontario Cancer Research Ethics Board (OCREB)

Date: May 11, 2011

RE: **Submission of External SAEs/SUSAR reports**

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OCREB submission requirements for reporting External Adverse Events is found in SOP 405A:

## 5.1 Criteria for Reporting External Adverse Events (EAE)

- 5.1.1 Upon becoming aware of an EAE that meets the reporting requirements for an unanticipated problem, (i.e., meets the criteria in 5.1.2), the investigator must report the external adverse event to OCREB. The PI may provide OCREB with a report prepared by the sponsor;
- 5.1.2 The Provincial Applicant should only submit the EAE report to OCREB if it is:
- Unexpected, AND
  - Related or possibly related, AND
  - Suggests that the research places research participants or others at a greater risk of harm, AND
  - Requires a change to the protocol and/or informed consent form and/or requires immediate notification to participants for safety reasons;
- 5.1.3 The EAE report must include **all** of the following information:
- the description of the serious and unexpected event
  - all previous safety reports concerning similar adverse events,
  - an analysis of the significance of the current adverse event in light of the previous reports, **and**
  - the proposed protocol changes, informed consent form changes or other corrective actions to be taken by the sponsor in response to the event;
- 5.1.4 Individual EAE reports that meet ALL of the above criteria must be reported to OCREB within 15 calendar days of the Provincial Applicant receiving the report;
- 5.1.5 The Provincial Applicant should continue to report unanticipated problems to the REB for the duration of the study (i.e., until the study is closed at all of the participating centres using OCREB or until the Provincial Applicant role is formally transferred to another participating PI.)

In regards to external SAEs/SUSARs that were issued since the IB cutoff date at the time of initial ethics submission, these should be reported to OCREB only if they meet the above criteria. If the criteria are met, the SUSARs should be summarized in a report that includes all of the elements listed in 5.1.3.

## References:

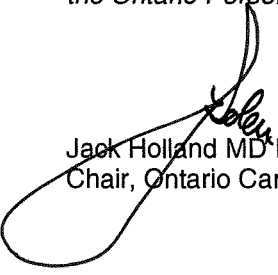
1. *OCREB SOP 405A Reporting External (Non-Local) Adverse Events*
  - [CAREB guidance document](#)
  - [History of CAREB guidance document](#)
  - [Health Canada response to CAREB guidance document](#)

**2. OHRP 2007 Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events:**

<http://www.hhs.gov/ohrp/policy/advevntguid.html#Q4>

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*The Ontario Cancer Research Ethics Board operates in compliance with and is constituted in accordance with the requirements of: The Second Edition of the Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans (TCPS 2); The International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations*



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