REVISED: August 2009

Centre for Addiction and Mental Health
Centre de toxicomanie et de santé mentale

Centre for Addiction and Mental Health
Serious Adverse Event (SAE) Report Form

This form should be completed for each serious adverse event report *and follow- up report* submitted and should accompany the more detailed account of the incident(s) provided to or by the external study sponsor (if any)

REB Ref # _____

Protocol Title: _____

Onset of SAE: ___/___/___ (dd mm yr) **Pt. study # (or SAE Identifier) : _____**

Hospital:_____ Principal Investigator:_____

Did this serious adverse event occur in Toronto? Yes____ No____

If this SAE occurred in Toronto, full follow-up details are required (attach separate sheet)

Statement of Principal Investigator

I acknowledge that I have read the information provided on the serious adverse event(s) and assessed its significance to patients and I am satisfied that, in light of this information:

1. The study should continue without change to the protocol Yes____ No____**

2. The study should continue without change to the consent form Yes____ No____**

*** If No, please enclose the amended protocol and/or consent form, in 3 copies, for review by the Committee*

3. For investigator-initiated trials, was SAE filed with Health Canada? Yes____ No____

Signature of Principal Investigator: _____ ____/____/____ (dd mm yr)

In the case of a local Serious Adverse Event, the person "medically responsible" (MRP) for the client/patient should sign this form.

Signature of MRP: _____ ____/____/____
(if applicable) (dd mm yr)

Date of Submission of SAE to REB: _____/____/_____ (dd mm yr)

Submit 3 sets (original + 2 copies of this form and attach to each, a copy of the detailed report) to:
Ms. Susan Pilon, CAMH – RS, 33 Russell Street, Room T116

REMINDER: Submit 1 complete copy by mail to:
Dr. Gary Remington, CAMH – CS, 250 College Street, 7th Floor, for Pharmacy & Therapeutics Committee