

# PROTOCOL DEVIATION REPORTING FORM

Protocol deviations that lead to an SAE should be reported within 48 hours, otherwise within 10 business days.

CAMH Protocol #(s): \_\_\_\_\_

**1. FULL PROJECT/STUDY TITLE:**

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**2. MAIN SPONSOR:**

**3. PRINCIPAL INVESTIGATOR:**

Title:	First Name:	Initial:	Last Name:

**4. SUBJECT I.D. NUMBER:** \_\_\_\_\_ or  N/A (if not subject-specific)

**5. DATE OF DEVIATION (yyyy-Mmm-dd):** \_\_\_\_\_

**6. DETAILED DESCRIPTION OF DEVIATION (Attached copies of any relevant documentation):**

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**7. DESCRIPTION OF CORRECTIVE ACTION TAKEN:**

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**8. DESCRIPTION OF ACTION THAT WILL BE TAKEN TO AVOID SIMILAR DEVIATIONS IN THE FUTURE?**

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**9. IF EXTERNALLY SPONSORED, HAS SPONSOR BEEN NOTIFIED OF THIS DEVIATION?**  YES  NO **If NO, please explain why not:**

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**10. HAVE YOU REPORTED THIS DEVIATION TO YOUR HEAD OF DEPARTMENT?**

YES  NO

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### 11. PERSON COMPLETING THIS FORM:

Title:	First Name:	Last Name:
Telephone ( <i>area code</i> ) 123-4567:	Extension:	Email:

_____	_____
<b>SIGNATURE OF PRINCIPAL INVESTIGATOR</b>	Date (yyyy-Mmm-dd)

Send two (2) signed copies of this form and any supporting documents to: Research Ethics Office, T117,  
33 Russell Street, Toronto, Ontario, M5S 2S1

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<b>CAMH REB CHAIR'S SIGNATURE</b>	Date (yyyy-Mmm-dd)