Deviation Form

Name of Investigator: CSERB Study #:

Title of Protocol: Date of Submission:

Please submit this completed form to report deviations from the written protocol or regulations.

Date of occurrence:	
1. This deviation involved:	
☐	A. Written Protocol ☐ Eligibility criteria ☐ Dose, dosage schedule, or use of device ☐ Standard Operation Standard ☐ Visit schedule ☐ Use of medications not allowed by protocol ☐ Other (specify): ☐ Lab Values ☐ Recruitment
☐	B. Health Canada Regulations (specify):
☐	C. Other (specify):
2. Describe the deviation and the net effect on risk:	
3. Was the deviation: ☐ Staff error ☐ Subject error ☐ Circumstance	
4. Explain why the deviation occurred:	
5. Explain what is being done to prevent future occurrences:	
6. Were participants adversely affected by the deviation? ☐ No ☐ Yes (if yes, explain):	
7. Was the participant informed of the deviation? ☐ No ☐ Yes (if yes, explain):	
8. Will the participant remain in the study? ☐ No ☐ Yes (if yes, explain):	

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Principal Investigator's Signature Date