CONCORDIA UNIVERSITY IRVINE

APPENDIX N: ADVERSE EVENT REPORT

All items must be filled in. If "Not applicable," explain why. This form and all related documents are submitted electronically to: irb@cui.edu

Researcher's Name	
Co-Researcher/s' Name/s	
Researcher/s' CUI Emails (unless not from CUI)	
Researcher/s' Phone Numbers	
Department	
Title of the Project & IRB #	
Date of Original IRB Approval	

Description of adverse event: *describe all circumstances related to this event. All hospitalizations and/or medical treatment must be reported. Include all notifications, correspondence, and other related materials related to the adverse event from the study sponsor or study sites. Include a statement regarding this adverse event and its relation to the study at Concordia University Irvine.*

To be completed by the IRB Reviewer

Date submitted

Notes:

Printed Name IRB Reviewer _____ Date _____

Signature of IRB Reviewer _____