



Institutional Review Board

Protocol #: _____

Date: _____

Adverse / Unanticipated Event Report

Institutional Review Board, Office of Academic Affairs

600 S. Michigan Avenue, Rm. 811M, Chicago, IL 60605

phone: 312-369-8795

email: IRB@colum.edu

Investigators are required to report serious and related events, when discovered during the course of research and no later than 2 working days after their occurrence. All other events must be reported when discovered during the course of research and no later than 5 working days after their occurrence.

Study Title: _____

Principal Investigator:

Phone:

Fax:

Columbia Email:

Date of Event:	Event occurred: Place an X in the appropriate column to the right.	<input type="checkbox"/>	at Columbia College Chicago
		<input type="checkbox"/>	At Off-Campus site

Describe Adverse or Unanticipated Event in the space below (include where the event occurred, severity, duration, action taken, outcome, personnel involved, and plan, if applicable):

In the opinion of the Principal Investigator:	Indicate "Yes" or "No"
Did this event cause harm to the participant or others?	
Was the event unanticipated?	
Was the event related to the research?	
Was the event reported to another IRB?	

Is this event listed:	Indicate "Yes" or "No"	Is a modification required:	Indicate "Yes" or "No"
In the protocol?		To the protocol?	
In the consent form?		To the consent form?	
		To other documents?	

Note: If modifications are required in the protocol and/or consent form, please attach two copies, one with and one without changes tracked.

If applicable, describe what plan has been implemented to ensure that this type of event will not occur again?

Please note that serious, related and unanticipated adverse events require full IRB review, and may warrant the suspension of new enrollment pending IRB review.

Original Signature of Principal Investigator	Date

Original Signature of Faculty Advisor	Date

Level of Original Review: Full Expedite: Exempt:

Protocol No. [Click here to enter text.](#)

Submitted	Reviewed	Status
STAMP	STAMP	STAMP