

Protocol Deviation Report (IRB-6)

Institutional Review Board, Office of Academic Affairs

600 South Michigan Avenue, Rm. 800M, Chicago, IL 60605

phone: 312-369-8795 email: irb@colum.edu

Investigators are required to report Protocol Deviations to the Institutional Review Board when discovered during the course of research but no later than 10 working days after their occurrence.

Study Title:

Principal Investigator:

Phone:

Fax:

Email:

Faculty Advisor (Only for student-initiated research):

Phone

Fax:

Email:

Date of Event/On-set:	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 Protocol Deviation (include where the event occurred, nature of event, action taken, outcome, personnel involved, and plan, if applicable):

Has this protocol deviation (or similar deviations) previously occurred in this study? *(If yes, please describe the event(s) and when the event(s) occurred.)* YES NO

In the opinion of the Principal Investigator, does this protocol deviation affect the safety of subjects? *(If yes, corrective actions must be stated in the space below, including measures taken to ensure that similar deviations do not occur in the future.)* YES NO

In the opinion of the Principal Investigator, does this protocol deviation affect the integrity of the study data? *(If yes, corrective actions must be stated in the space below, including measures taken to ensure that similar deviations do not occur in the future. Attach a separate sheet, if necessary.)* YES NO

If modifications are required in the protocol or consent form, please attach two copies.

Please note that if this event causes or increases the risk of physical or psychological harm, or loss of privacy or confidentiality to a research participant or others, an IRB-4 ADVERSE EVENT REPORT FORM must be submitted to the IRB.

Original Signature of Principal Investigator	Date