

**Adverse Event (AE) Reporting Form  
Institutional Review Board (IRB)  
Chicago State University**

Principal Investigator:  
Email Address:  
Phone Number:  
CSU Extension:

IRB Protocol #:

Project Title:

**Adverse Event (AE) Information:**

1. Study Location (please check one):  Chicago State University  Other (List all sites involved):
2. Location of Adverse Event:  Chicago State University  Other: \_\_\_\_\_
3. Seriousness of Event:  Non-Serious  Serious but not Life Threatening  Life Threatening
4. Required Care:  Emergency Room / Physician: \_\_\_\_\_  
 Clinic: \_\_\_\_\_  
 Counseling/Referral: \_\_\_\_\_  
 No additional care was sought \_\_\_\_\_

5. Event Cause: In your judgment, how likely was the AE caused by the procedures in this protocol?

- Not related
- Unlikely
- Possibly
- Probably
- Definitely

6. Consent Form: Is the risk of this adverse event contained in your consent form?  Yes  No

7. Notification: Will participants currently enrolled in the study be notified of this event?  Yes  No

**Adverse Event Summary:** Attach a detailed summary describing the circumstances of the adverse event.

Include responses given by the subject and the investigator.

If relevant, include procedures taken to prevent similar incidents.

In your judgment, should the consent form or any portion of the study be revised as a result of this event?

- Yes. An application for continuing review will be submitted to the CSU IRB indicating the nature of the amendment or modification within 10 days of receiving this adverse event reporting form. If an amendment is not received within 10 days, I understand that my protocol may be suspended.
- No. Although the event was possibly, probably or definitely caused by the study and the risk is not identified in the consent form, I do not wish to amend the protocol for the following reasons (use additional pages as needed).

(please see reverse side)

PI Certification:

I certify that the adverse event information provided is accurate to the best of my knowledge. Further, I agree to submit a completed and *original* adverse event reporting form along with the required summary of events.

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Supervising Faculty Member

\_\_\_\_\_  
Date

FOR CSU IRB USE ONLY:

Date Received: \_\_\_\_\_