Adverse Incident Report

INSTITUTE FOR CLINICAL SOCIAL WORK

Principle Investigator: _____

Study Title: _____

Section 1:

1.1 Does this adverse event represent a "serious adverse experience?"

Yes _____ No _____

[A "serious adverse experience" is defined as any experience that suggests a significant hazard, contraindication, or side effect. This could be a serious adverse cognitive or emotional experience which includes any experience that is fatal or life-threatening, or regression that is traumatic and requires inpatient hospitalization, or possibly fosters self harm or harm of others.]

1.2 Is this an "unexpected adverse experience?"

Yes _____ No _____

[An "unexpected adverse experience" means any adverse experience that is not identified in nature, severity, or frequency in the consent in the risk information provided in the general investigational plan or in the consent to participate.]

1.3 Is this adverse event clearly or possibly related to the research process?

Yes _____ No _____

NOTE: If you answered Yes to any of these questions, you must complete Section 2, below.

Section 2:

Date of incident: _____
Place of the incident: _____
Person reporting an adverse incident: _____
Relationship to the project: _____

2.1 Has the subject had a previous adverse event on this study? Yes _____ No _____

2.2 Attribution of incident: (Check one)

_____ Not or unlikely to be related to research content, process or procedure
_____ Probably or definitely related to research content, process, procedure
_____ Unknown

2.3. Provide a brief rationale for this attribution:

2.4 Summarize the nature of the adverse event, the circumstances under which it occurred, and the outcome.

2.5 In your opinion, is a change in the research protocol necessary to minimize risks to current and future subjects? Yes _____ No _____

If yes or no, please explain:

2.6 In your opinion, are any changes in the consent form required to provide adequate safety information to current and/or future subjects? Yes _____ No _____

If yes, please provide an updated consent form for committee review. If no, please explain:

2.7 Is it necessary to inform subjects currently enrolled in the study about a change in the risk/benefit profile? Yes _____ No _____

If yes, describe how you intend to accomplish this:

Principal Investigator: _____ _____
Signature Date

Submit completed form to: Chair of the IRB
Institute of Clinical Social Work
200 N. Michigan Ave., Suite 407
Chicago, IL

IRB Use Only

_____ Expedited review sufficient _____ Full committee review necessary

Action:

_____ Continue study as submitted and approved by IRB. No changes necessary.
_____ Updated consent form should be submitted by principal investigator.
_____ Place study on hold pending further review and investigation
_____ Recommend changes in protocol and/or consent document
_____ Report to IRB chair: (Date) _____

Reviewer's comments:

Reviewer's Signature _____ Date _____

Chair's Signature _____ Date _____