Incident Report Form

Directions: All incidents (minor issues, protocol change/deviation, unanticipated problems or adverse events) need to be reported by the principal investigator/project evaluator/researcher directly to HIRB within 10 calendar days from the date of discovery. In addition, for the more severe problems or events, the project sponsor or funding agency must also be notified. For more information on incident reporting, the FDA has a guidance document that can be accessed at
http://www.fda.gov/downlaods/RegulatoryInformation/Guidances/UCM126572.pdf

Project Investigator Name: _____
Project Name: _____
Date of occurrence: _____(mm/dd/yyyy)
Date Investigator became aware of occurrence: _____ (mm/dd/yyyy)
Address of site where incident took place:
_____

1) Please, check the ONE box below that most appropriately describes the incident being reported. Next, more fully describe the incident, any corrective action taken, and the preventive measures now in place to ensure no future occurrences.

Protocol Changes/Deviations		**Consent Process Violations**		**Unexpected Outcome**	
	Inclusion criteria		Participant screened prior to receipt of consent		Unexpected Event not listed in the informed consent form
	Exclusion criteria		Participant involved without receipt of consent		Reasonable Possibility that Unexpected Outcome Derived from Protocols
	Delay of protocol delivery		Unofficial, unapproved or incorrect version of consent form used		Participant Physically or Psychologically Harmed: Related to protocol
	Participants placed in wrong group		English consent form used with non-English speaking participant		Participant Physically or Psychologically Harmed: Not related to protocol
	Incorrect version of assessment used		Other		Breach of confidentiality
	Other				Other

2) **Describe in the text box below a complete description of the deviation/violation.**

3) **Describe any corrective action that was taken, by whom, at what point in the process, and the results of said corrective action, etc. in the text box below.**

4) **In the text box below, describe the current preventive procedure(s)/measure(s) that are now in place to prevent a recurrence of similar incidents.**

5) Please, answer each question below by checking "Yes" or "No."

Question	Yes	No
A. Has the Funding Agency or Project Sponsor been notified?		
B. Has the Funding Agency or Project Sponsor provided a written exemption for this deviation/violation/event?		
C. Has this incident increased the potential for risk to the participant(s) or others?		
D. Has this incident affected the overall integrity of the research study or program evaluation design?		
E. Do you perceive this incident as a one-time occurrence?		
F. Has this incident resulted in a major change to the research protocol or evaluation design's protocols?		
G. Has this incident resulted in a major change to the participant consent forms?		
H. Has this incident resulted in a new monitoring requirement for the study or program?		
I. Has this incident resulted in the implementation of new safety procedures where the study or project is being held?		
J. Is the affected participant(s) still participating in the study/program?		

6) Complete the information below, then sign and date the form and return an electronic to HIRB.

Form Preparer Name's (please, print): _____

Telephone: (_____) _____-_____

Fax: (_____) _____-_____

Email: _____

Date form completed: _____(mm/dd/yyyy)

In the submission of this form, the signer below certifies that the information contained in this report is complete and accurate. No significant facts have been omitted, misrepresented, falsified or misstated.

_____

Signature Date