Complete form electronically. Save and send as an attachment to IRB Chair Lindsay Walker at walkerln@delhi.edu **Please use SUNY Delhi webmail. All paperwork is electronically filed.**

State University of New York at Delhi
Institutional Review Board
Adverse Event Reporting Form
(adopted with permission from University at Albany)

For IRB use only
Date Received:

Investigators are required to report any adverse event that occurs during the protocol approval period.

An adverse event form must be completed and submitted to the IRB within 5 working days of the occurrence.

In the event of a *serious* adverse event, the IRB Chair, Lisa Heimbauer, should be notified *immediately* by telephone: 607.746.4138 with a follow-up written report.

The IRB definition of adverse event is an experience, the nature, severity or frequency of which is not consistent with the current risk information described in the investigational plan, or protocol, or consent form.

An adverse event is any occurrence or situation during the course of a research project that was:

1) harmful to a subject taking part in the research, or

2) increased the probability of harm to subjects taking part in the research such as

a. physical injury to a participant;

b. psychological, social, or economic harm to a participant;

c. breaches of protocol, such as breakdowns in the informed consent process, violations of confidentiality of data or privacy of a participant, & complaints by participants or their representatives; and

d. any serious or continuing noncompliance with federal regulations by investigators or research staff.

Note: Adverse events vary in their seriousness. The death or serious injury of a research subject is a *serious* adverse event. Social and behavioral interviews and studies that deal with sensitive issues may also give rise to adverse events, such as research subjects may become very upset because of the nature of questions. Another risk to participants is the unintentional release of their identities or personal information about them such as through the loss of a computer with relevant data. Negative, non life-threatening physical reactions to drugs administered in a study, or physical consequences from dietary restrictions (e.g. fainting) are also adverse events that must be reported. Unexpected accidents that occur in the course of a research project, for example, a subject in an exercise study falling off an exercise bike or treadmill, should also be reported. All of these types of events qualify as adverse events that investigators must report.

Date of Report				
Protocol Number				
Protocol Title				
Primary Investigator Name / Contact Information (Provide contact information where we can reach you regarding this project.)	**PI Name**	**Address** (*campus or business)*	**Email Address**	**Phone Number(s)**
Faculty Advisor Name / Contact Information (Required when PI is a student.)	**Name**	**Department & Campus Address**	**Email Address**	**Phone Number(s)**

1. **Date of Adverse Event:**

2. **Describe the adverse event(s):** *(Include the number of participants affected, where the event occurred, relevant participant history and any direct observations that occurred prior to the event.)*

3. **Did the participant withdraw from the study as a result of the adverse event?**
   ☐ Yes ☐ No

4. **Describe any actions taken or treatments/interventions provided to participants to resolve the event.**

5. **Has the same event been previously reported for this study?** ☐ Yes ☐ No

   - If **YES**, how many times to date?
   - **If Yes**, provide the date of the most recent event.

6. **Does this event require any changes in research procedures or the informed consent?** ☐ Yes ☐ No

   - If **YES**, describe how you are going to inform currently enrolled patients of the changes?
   - If **YES**, you are required to submit a modification request form with all necessary changes within 2 weeks of the date of this report.

7. **To whom has the adverse event been reported to or will be reported to?** Check all that apply and identify by name.

Attach additional pages if necessary.

Co-Investigator(s):	☐	Sponsor(s):	☐	Collaborating Institutional IRBs:	☐
Key Personnel:	☐	Other – please explain:	☐		

Please attach any additional information as necessary.

PRINCIPAL INVESTIGATOR ASSURANCE: By signing this form you are acknowledging the following:

- You are conducting this research in compliance with SUNY Delhi Policies, federal, state and local laws, Declaration of Helsinki and the Belmont Report and have reported all known adverse events.

Print Principal Investigator Name	**Principal Investigator Signature**	**Date**

FACULTY ADVISOR ASSURANCE (if applicable): By signing this form you are acknowledging the following:

- You are overseeing the conduct of the research for compliance with SUNY Delhi Policies, federal, state and local laws, Declaration of Helsinki and the Belmont Report and will promptly report any deviations to the IRB.

Faculty Advisor Name	**Faculty Advisor Signature**	**Date**

Version 8/2018