Eastern University Institutional Review Board
Adverse Effect/Event Report Form

(To be completed by the Principal Investigator)

Instructions: Inform the IRB via e-mail (irb@eastern.edu) of your intent to submit an Adverse/Effect Report before completing this form. Once the form is completed, submit it to the "Adverse Effects Forms" folder in the Assignments area on the IRB Brightspace site.

Type or print (answer all questions):

Principal Investigator:

Contact Person:

E-mail:

Phone: Fax:

Sponsor:

Sponsor email address:

Title of Protocol:

Event Date:

Date event reported to PI:

Event report: ☐ Initial ☐ Follow-Up
If a Follow-Up, give the date when the Initial Adverse Effect Form was submitted:

Site: ☐ EU campus ☐ External site
If External site, please give the name of the site:

Brief description of the event:

Action taken:

Causality: ☐ Definite ☐ Probable ☐ Possible ☐ Unrelated

Event Severity Classification: ☐ Serious Unexpected ☐ Moderate Unexpected

Protocol Modification: Is it your intention to modify the protocol/consent form to address increased monitoring for this adverse event or to provide new information to the research subject?

☐ Yes and I will submit a modification request form with revised protocol and/or consent documents.

☐ No. Explain rationale:

DECLARATION: I certify that I have reviewed the attached report and conclude that the risk-benefit ratio of the research continues to be acceptable, and that the risks are minimized to the greatest extent possible. By signing below, I certify that the information contained in this report is correct.

Principal Investigator:

_____	_____	_____
Signature	Print Name	Date

Faculty Sponsor: (if P.I. is a student)

_____	_____	_____
Signature	Print Name	Date

The EU-Institutional Review Board:

_____	_____	_____
IRB Chair Signature	Print Name	Date