



WORCESTER POLYTECHNIC INSTITUTE
Institutional Review Board
Adverse Event Reporting Form

WPI IRB use only	
IRB #	_____
Date:	_____

Serious or unexpected adverse reactions or injuries experienced by subjects from their participation in a WPI IRB approved study must be reported to the WPI IRB within 48 hours. Other adverse events should be reported within 10 working days. *A serious adverse event can be any serious undesired and unintended, although not necessarily unexpected, effect of the research occurring in subjects as a result of the interventions or interactions used in the research, or from the collection of privately identifiable research data.*

Please answer every question. Positive answers should be amplified with details. You may mark N/A where the question does not pertain to your application. Any incomplete application will be rejected and returned for completion.

1. Title of Study

2. Investigator

Name: _____ Building and Room #: _____
Title: _____ E-mail: _____
Department: _____ Phone: _____

I. BASIC INFORMATION

II. ADVERSE EVENT *(Provide attachments as needed.)*

1. Description of Adverse Event. *(Please provide a detailed description.)*

a. Date of the adverse event.

b. Nature of the injury to the subject. *(Please provide a detailed description.)*

c. Relationship of the adverse event to the protocol. *(Please provide a detailed description.)*

2. Treatment of the Subject. *(Describe the treatment provided to the subject and indicate if the subject recovered.)*

Signature of Principal Investigator: _____ Date: _____

Please return a signed hard copy of this application to the WPI IRB c/o Ruth McKeogh 2nd Floor, Project Center. If you have any questions, please call (508) 831-6699.

FOR WPI IRB USE ONLY:

This report was reviewed and accepted by the WPI Institutional Review Board on:

_____, as certified by _____.