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 __________________________.