**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.*

**I. BASIC INFORMATION**

|  |
| --- |
| **1. Title of Study** |
|       |
| **2. Investigator** |
| Name:  |       | Building and Room #: |       |
| Title:  |       | E-mail:  |       |
| Department:  |       | Phone:  |       |

**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 . |