**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.***

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| **FOR WPI IRB USE ONLY:**  This report was reviewed and accepted by the WPI Institutional Review Board on:  , as certified by . |