Hello and thank you for accessing this form from the University of Maryland, Baltimore County Institutional Review Board web site.

Prior to submitting, please ensure that spelling and grammar are correct; this will assist in the timely review of this form during the IRB evaluation process. Complete all sections of the protocol application (indicate N/A in the section not applicable to your protocol). "See attached proposal" or “See the previous section” are not an acceptable responses.

Enter information by clicking the  box or typing in the **Click here to enter text.** area.

**Please go to UMBC** [**IRB website**](http://research.umbc.edu/institutional-review-board-human-subjects/) **for all up-to date guidance and information regarding the below questions.**

Investigators with approved human participant research projects are responsible for reporting any serious injuries, adverse events or unanticipated negative effect experienced by a research subject that is possibly, probably or definitely related to study procedure(s). Any unanticipated negative effect or undesirable experience associated with the research procedure(s) might be considered an adverse event. The event is considered serious and must be reported when the participant experiences an unusually strong response, recurring problems, and/or death.

**Reports of adverse events occurring on UMBC protocols are to be submitted to the IRB Chair *within five (5) days of occurrence,* after first awareness of the problem.**

The IRB may determine if the study and/or consent form should be updated, and/or currently enrolled subjects should be informed of the new information to determine whether they wish to continue, or that the risk to subjects has changed such that the study must be stopped.  If the adverse event affects the protocol, investigators will be notified of the appropriate changes to make for submission to the IRB for review and approval. Any changes will be submitted in the form of an amendment.

Protocol Number: Click here to enter text.

Protocol Title: Click here to enter text.

| Investigator(s) | Department | Phone Number | E-mail |
| --- | --- | --- | --- |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

Original Protocol Approval: Full Board  Expedited

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| Subject Identifier: Click here to enter text. | Gender: Click here to enter text. | Age: Click here to enter text. |
| --- | --- | --- |
| Date of occurrence: Click here to enter a date. | Location: Click here to enter text. |  |

Did this event occur to a subject enrolled in your study? Yes  No

Was this event attributable to a study procedure? Yes  No

Was the event unexpected? Yes  No

Was the event more serious than expected? Yes  No

Is this kind of adverse event described in the current consent form? Yes No

Has this type of event been reported before? Yes  No

In your judgment, is a change to procedure necessary to Yes  No

eliminate or reduce risk?

**(If yes, submit a modification request and attach to this report for review)**

Will the event require changes to the consent form? Yes  No

**(if yes, submit a modification to the consent form and attach to this report for review)**

**Describe the adverse event and action taken**

Click here to enter text.

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***Note: Copy the above in this for additional participant information***

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Investigator’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator’s Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

**IRB Action**:

**Continue study as submitted and approved by the IRB. No changes needed**

**Review recommended changes to protocol or consent form**

**Place study on hold and discuss with Investigator(s)**

**Report to Institution officials: Date:** Click here to enter a date.

Signature - IRB Chair ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Electronically submit this and any accompanying documents to** [**irbsubmissions@umbc.edu**](file:///C:\Users\sparklin\AppData\Local\Box\HARPO\IRB\irb%20forms\irbsubmissions@umbc.edu)**.**

(adverse event report form) – 02/01/2016