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.

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.**

**This form must be used to report protocol deviations, defined as unreported changes in the IRB approved protocol or consent documents, misuse *or* non-use of the IRB approved informed consent documents, lapse in approval for continuing review, failure to obtain IRB approval prior to starting research activities**

**Investigators who fail to comply with regulations may result in the individual investigator's ability to conduct research but can also affect the ability of all others at UMBC to perform human participant research.**

IRB #: Click here to enter text. Investigator(s): Click here to enter text.

Protocol Title: Click here to enter text.

Date Submitted: Click here to enter text.

**Describe the deviation:** Click here to enter text.

**This deviation:**

**does not** increase the risks to participants in the approved protocol

**does** increase the risks to participants in the approved protocol

**Was the deviation due to:**  Investigator error  Subject error  Circumstance

**Explain why the deviation occurred:** Click here to enter text.

**Explain what is being done to prevent future occurrence** Click here to enter text.

**Was/Were participant(s) adversely affected by the deviation?**  Yes  No

**If yes, explain (submit an adverse event reporting form)** : Click here to enter text.

**Was/Were the participant(s) informed of the deviation?**   Yes  No

**If no, explain**: Click here to enter text.

**Will the participant(s) remain in the study?**   Yes  No

**Will the research study continue?**   Yes  No

**Electronically submit the protocol and any accompanying documents to** [**irbsubmissions@umbc.edu**](file:///\\sharedvol.ad.umbc.edu\Dept\ORA\HARPO\IRB\irb%20forms\irbsubmissions@umbc.edu)**.**

By typing your name, email address and date, the investigator(s) certify they will abide by all UMBC IRB policies and procedures and understand that no research activities will be conducted with human participants prior to obtaining the required approvals.

Investigator’s Signature: Click here to enter text. Email: Click here to enter text. Date: Click here to enter a date.

Faculty Advisor's Signature: Click here to enter text. Email: Click here to enter text. Date: Click here to enter a date.

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**IRB Action**

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Reviewed by the IRB Chair/Date

(protocol deviation reporting form) – 02/01/2016

[compliance@umbc.edu](mailto:compliance@umbc.edu)