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.**

Protocol Title: Click here to enter text.

The use or disclosure of Protected Health Information (PHI)*1* involves no more than a minimal risk to the privacy of individuals. The IRB may waive or alter the requirement to obtain authorization from research subjects in order to use or disclose their protected health information, provided that the investigator justifies, and the IRB agrees, that specific criteria have been met.

HIPAA regulations require reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Explain why PHI obtained for this study is/are the minimum information needed to meet the research objectives. All researchers are accountable for any PHI released under a waiver.

Click here to enter text.

Explain, in terms of this project, how PHI will be collected and a list of the source(s) of the PHI.

Click here to enter text.

Describe the plan to protect PHI, indicate where the PHI will be stored and who will have access.

Click here to enter text.

All PHI collected during the study will be destroyed at the earliest opportunity consistent with the conduct of research. Describe the procedure used to destroy PHI collected during the study (electronically, paper, audio/video, photography, other). If PHI collected during the study will not be destroyed, please explain.

Click here to enter text.

The research could not practicably be conducted without the waiver because (explain below):

Click here to enter text.

The research could not practicably be conducted without access to and use of the PHI because (explain):

Click here to enter text.

The information listed in the waiver application is accurate and all research staff*2* will comply with the HIPAA regulations and the waiver criteria. The investigator assures that PHI obtained as part of this research will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entity I will seek approval by the IRB.

Investigator’s Name:Click here to enter text. Date: Click here to enter text.

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*1 - PHI: individually identifiable health information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that relates to the past, present or future physical or mental health or conditions of an individual plus any of the 18 identifiers listed in the regulations.*

*2- Note: Research staff is defined as ALL study personnel (including PI) that is involved in the research and currently listed in the IRB protocol application*

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

**IRB Action**:

Approved - IRB Chair ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(hipaawaiver.doc) –09/10/2015