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 Approval Number: Click here to enter text.

Protocol Title:  Click here to enter text.

Investigator(s): Click here to enter text.

Federal regulations at [45 CFR 46.117](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm%2346.117) require written informed consent (meaning the use of an IRB-approved

written consent form which is signed by the participant or the participant's legal representative). Occasionally

there are reasons to waive written consent or to alter the requirements of consent. Researchers are required to inform participants in written or verbal form of the primary purpose of the research project and of any procedures which they will undergo. The IRB will ask you to describe how consent conversations will be documented (consent log, spreadsheet, etc.) Additionally, participants are to be informed of their rights regarding the study (voluntary participation, protecting anonymity and privacy) and any risks or benefits associated with the project.

The IRB determines which type of consent applies to your research but please indicate the type that you recommend. Attach this request to the protocol.

**Waiver of Documentation of Informed Consent (Waiver of Signed Consent)** (complete Section A)

**Waiver of Informed Consent** (complete Section B)

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**Section A**

**Waiver of Documentation of Signed Consent)** (i.e. initials, signature).

The IRB may waive the requirement to obtain a signed consent form for some or all participants if at least one of the following applies to the research:

* The research involves no more than minimal risk of harm to the participants and involves only procedures that do not require written consent outside of research. (45 CFR 46.117 (c) (1)).  *(For example, the only record of the name or other identifying information of the subject would be the signed consent form and knowledge of an individual's participation or information provided could lead to potential legal, social, or physical harm.)*
* The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the subject wants documentation linking the participant with the research, and the participant's wishes will govern.(45 CFR 46. 117 (c) (2).  *(For example, the*evaluation of the effectiveness of a smoking cessation program among its participants. The anonymous questionnaire containing no personal identifiers will be administered after the completion of the program.

**Choose one of the below and provide justification:**

**Yes**, my study meets at least one of these requirements.

**Please provide justification for waiving documentation of consent that is specific to your study:** Click here to enter text.

*[Please explain how, in the absence of signed written consent forms, consent will be documented, e.g. tape recordings, videos, chart notes, etc.]* **This justification MUST be included in the “Consent” section of the IRB application. Check the below on which process will be used to record consent:**

Audio recording

Video recording

Web based (on-line) consent acknowledgement box

Information Sheet

Other(s) - Please specify: Click here to enter text.

**No,** my study does not meet either of these requirements. DOCUMENTATION OF INFORMED CONSENT CANNOT BE WAIVED. If applicable a Waiver Of Informed Consent may be requested (below).

**Section B**

**Waiver of Informed Consent Requirements**

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement for informed consent provided the HRRB finds and documents that all of the following criteria below are met [45 CFR 46.116 (d)(1-4)]: *(For example, a psychological study that is actually about peer pressure, but participants are told the study is about perception of visual phenomenon.  Deception is required to adequately measure peer pressure).*

* The research involves no more than minimal risk to the participants. The waiver or alteration will not adversely affect the rights and welfare of the participants.
* The research could not practicably be carried out without the waiver or alteration. Whenever appropriate, the participants will be provided with additional pertinent information after participation

**Choose one of the below and provide justification:**

**Yes**, my study meets all of these requirements.

**Please provide justification for waiving informed consent that is specific to your study:**

| Which elements of Informed Consent will be altered  \  participation involves research  purposes of the research  duration of participation  procedures to be followed  identification of experimental procedures  foreseeable risks / discomforts  benefits to subjects or others  appropriate alternatives advantageous to subject  maintenance of confidentiality  for more than minimal risk research, compensation / treatment available in case of injury  voluntariness of participation  no penalty for refusal to participate  may discontinue participation without penalty  contact for questions about research  contact for questions about participants’ rights |
| --- |

**No**, my study does not meet all of these requirements. INFORMED CONSENT CANNOT BE WAIVED. If a Waiver of Informed Consent is not applicable, you WILL need to submit a signed consent document.

**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.

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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Approved, IRB Chair/Date

(request for waivers of consent form) – 09/10/2015