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.

|  |  |
| --- | --- |
| I am applying for: (check one or both) | |
| Alteration of elements of informed consent | Waiver of elements of informed consent |

**Section I.**

According to the basic elements of informed consent, the following information should be provided to each subject. Please check the box next to the element (s) you are requesting to alter or waive and proceed to the questions below.

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental

(2) A description of any reasonably foreseeable risks or discomforts to the subject

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

**Section II.**

Please provide a response to the following questions as they apply to your research. To qualify for IRB approval, you must provide a response to **ALL** of the following questions. Please be specific in explaining why each statement is applicable to your research.

|  |  |
| --- | --- |
| **1) The research in its entirety involves no more than “minimal risk” to participants.** | Yes  No |
| *Explain:* | |
| **2) The waiver or alteration will not adversely affect the rights and welfare of the participants.** | Yes  No |
| *Explain:* | |
| **3) The research could not be practically carried out without the waiver or alteration.** | Yes  No |
| *Explain:* | |
| **4) Whenever appropriate, participants will be provided with additional pertinent information after participation.** | Yes  No |
| *Explain:* | |

**If yes, 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.