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.**

| Investigator(s) | Department |
| --- | --- |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| Protocol # Click here to enter text. | Title Click here to enter text. |

**Continuation year # 1** [ ]  **Continuation year # 2** [ ]  **Continuation year # 3** [ ]  **Continuation year # 4** [ ]

A protocol is initially approved for a period of up to 12 months, unless otherwise specified by the IRB. **A continuation** (renewal) may be requested, each for a period of up to 12 additional months, unless otherwise specified by the IRB.

All questions must be answered in narrative style; "yes", "no", or "none" are not acceptable. The principal investigator is responsible for timely submission of a continuation (renewal) request application.

Please review and check the below to determine if your renewal qualifies for expedited review (extracted from [Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm) - effective November 9, 1998).

8) Continuing review of research previously approved by the IRB at a convened meeting where now the research:

[ ] a) is permanently closed to the enrollment of new subjects, all subjects have completed all research related interventions, and the research remains active only for long-term follow-up of subjects; **OR**

[ ]  b) had no subjects ever enrolled and no additional risks were identified; **OR**

[ ]  c) where the remaining research activities are limited to data analysis.

9) [ ]  Continuing review of research, where the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**Electronically submit the protocol and any accompanying documents to** [**irbsubmissions@umbc.edu**](file:///%5C%5Csharedvol.ad.umbc.edu%5CDept%5CORA%5CHARPO%5CIRB%5Cirb%20forms%5Cirbsubmissions%40umbc.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.

**Approvals of continuations via expedited review will take approximately two (2) weeks**

(annual continuation report form) –07.31/2018

| **1) Have there been any substantive changes to the level of risk since the original** **submission or the last continuation report?** [ ] **Yes** [ ]  **No If yes, please explain:** Click here to enter text. |
| --- |
| **2) What are the plans for the continuation of the protocol?** Click here to enter text. |
| **3) Do you have plans to contact or follow-up with participants during the continuation period?** [ ] **Yes** [ ] **No** |
| **4) How many participants are currently enrolled in this project?** Click here to enter text. |
| **5) How many participants do you anticipate enrolling in the next continuation period?**  Click here to enter text. **Has there been any change made to the participant selection process?** [ ] **Yes** [ ]  **No** |
| **6) How long will it take, from now, to enlist the number of participants required by the protocol?** Click here to enter text. |
| **7) What changes have you submitted in the protocol since the original approval OR the last continuation approval? Has there been any change made to the participant selection process?** [ ] **Yes** [ ]  **No List the dates submitted and a brief summary of the modification:** Click here to enter text.**If you are contemplating changes in the protocol, please detail here *(NOTE – a separate modification form is not required to submit with the renewal.)*:** Click here to enter text. |
| **8) Has there been any changes/additions in sponsored funding?** [ ] **Yes** [ ] **No****Please state below the Proposal or Award ID and Award Title and briefly describe new research methods (if any). All changes must be added to the existing protocol document. Attach a copy of the components of grant applications and contract proposals related to human subjects use [e.g. the Human Subjects section] as well as any amendment if it involves changes or additions to sponsored funding (e.g. submission of JIT materials, confirms to an agency that a grant has IRB approval, or adds a new award to an existing protocol).**Click here to enter text.**Has there any changes to any previous conflict of interest disclosure, as described by** [**UMBC’s Conflict of Interest**](http://www.umbc.edu/research/ORPC/coi_procedures_umbc.html) **policies?** [ ]  **Yes** [ ] **No** [ ]  **N/A** |
| **9) Will any research team member pursue an individual thesis, Master’s level or dissertation research project associated with the participants or collected data of this protocol?** [ ] **Yes** [ ] **No. Please describe who and provide the title of this research project (should match the submitted Student Research Notification)** Click here to enter text. |
| **10) Has there been a change to the consent form or the informed consent procedure since the original submission or last continuation?** [ ] **Yes** [ ]  **No Attach currently approved copies of consent/assent forms.**  |
| **11) Did all participants receive a copy of their consent forms?** [ ] **Yes** [ ]  **No** |
| **12) Did you consent non-English speaking participants?** [ ] **Yes** [ ]  **No** [ ]  **N/A If yes, please describe the consent process** Click here to enter text. |
| **13) If collecting human biological specimens, have there been any changes to the procedures you and the research team are using to minimize or eliminate exposure to potentially infectious agents?** [ ] **Yes** [ ]  **No** [ ]  **N/A****If yes, please explain:** Click here to enter text. |
| **14) In research that uses data, records or human biological specimens without direct participant contact, has there been any changes in any approved data use agreements, the source of the data or specimens and how were they collected?** [ ] **Yes** [ ]  **No** [ ]  **N/A** **If yes, please explain:** Click here to enter text. |
| **15) Are there any results to report?** [ ] **Yes** [ ] **No If so, please attach a summary.**  |
| **16) Have you encountered any adverse effects as a result of or coincidental with the protocol? If yes, how many adverse reactions were encountered?** [ ] **Yes** [ ]  **No** [ ]  **N/A Indicate how the continuation of this research will address or attempt to prevent such effects in the future and include a listing of citations of relevant research.**Click here to enter text. |
| **17) Where are the consent forms and identifiers of all research participants kept? What provisions do you have in place to ensure confidentiality of data (coding system, locked or restricted access)? If there are no research subjects, indicate no subjects.**Click here to enter text.  |

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**IRB Action**

**Recommendations and Action:**

**IRB Chair Approval:** Click here to enter text. **Date:**Click here to enter text.

**Period of continuation approval from** Click here to enter a date. **through** Click here to enter a date.