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. Complete all sections of the protocol application (indicate N/A in the section not applicable to your protocol). "See attached proposal" or “See the previous section” are not an acceptable responses.

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.

Is this application associated with a Planning and Development activity? If yes, please provide the date the ORPC provided administrative approval, the IRB approval number and title: Click here to enter text.

List ALL funding sources that will support the human subjects work described in this protocol (if pending, indicate submission date). **If none, check this box** [ ]

|  |  |  |  |
| --- | --- | --- | --- |
| **Award Title** | **Funding Agency** | **Project Dates** | **Proposal or Award ID**  |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
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List all project personnel below.

| Name | Department | Phone Number | E-mail | Date CITI Education Program was completed \* | Describe role in the project |
| --- | --- | --- | --- | --- | --- |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter a date. | Click here to enter text. |
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**\* If you need information about training completion dates, please contact the ORPC**

Do the Investigator(s) or any of the project personnel have a financial interest related to the research or sponsor (e.g. payment for services, equity interests, etc.) that must be disclosed according to any of [UMBC’s Conflict of Interest policies](http://research.umbc.edu/conflicts-of-interest-and-commitment/)?

Yes ☐ No ☐

Will the procedures in this application be used for (chose the applicable one): URCAD project [ ]  honors thesis, master’s thesis[ ] , or dissertation research [ ] ?

For thesis or dissertation research ***only***, please list committee member names: Click here to enter text.

Planned graduation date?Click here to enter a date.

**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)**.**

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

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

***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. The investigator(s) will inform the IRB at the earliest possible date of (1) any significant changes in the project with respect to human subject participation, (2) any adverse reactions or unexpected responses observed involving human participants, and (3) any need for continuation of the project activities beyond the approval date. The investigator(s) certify all personnel working on this protocol have completed the appropriate CITI training and received adequate and proper training in research procedures.***

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

***Faculty advisors who type their name, email address and date certify they have read and reviewed this proposal and confirm it is ready for review by the IRB. Faculty advisors agree to mentor the student and assist the student with the resolution of problems or concerns during the term of IRB approval***

**Please use this application only for projects falling within exemption categories 1, 2, 3, and 6**

**PROJECT INFORMATION**

**Anticipated Duration of Study:**

From Click here to enter a date. to Click here to enter a date.

**NOTE: The project may not start until a final exemption determination is issued.**

**Provide a lay summary of the study, including the purpose and the research questions and hypothesis to be evaluated.**

Click here to enter text.

**Who are the proposed participants?**

Click here to enter text.

**Describe ALL research/data collection locations:**

Click here to enter text.

**Describe the tasks or procedures that the participants will perform for each phase of the study. Provide details about the types of surveys or interviews (individual or focus groups), if observation is involved, how will data be collected (Internet surveys, telephone interviews, audio/video recording), etc. If research is conducted in a classroom setting, during class time, describe the alternative activity for those participants who do not choose to participate. Include the estimated length of time for each procedure, any manipulation that may cause discomfort or inconvenience and plans for follow-up. *Copies of questionnaires, survey instrument(s), interview/focus group questions MUST be included with this application.***

Click here to enter text.

**EXEMPTION CATEGORIES**

Please select the appropriate category in which you believe the project exemption applies and respond to questions in the selected exemption category. Then, continue with the remainder of the application to explain the proposed study.

[ ]  **Category 1 [(§46.104(d)(1)]:** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to ***adversely impact students' opportunity to learn*** required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Describe the established or commonly accepted educational setting of the research:

Click here to enter text.

Could the research adversely impact student achievement in anyway?

[ ] No [ ] **Yes** **(The study does not qualify under this exemption category – please see the** [Expedited review](http://research.umbc.edu/expedited-review-process/) procedures**)**

Could the research adversely impact the assessment of educators who provide instruction?

[ ] No [ ] **Yes** **(The study does not qualify under exemption category– please see the** [Expedited review](http://research.umbc.edu/expedited-review-process/) procedures**)**

Does the research involve a comparison of a proven educational technique to a novel technique?

[ ] No [ ] **Yes** **(The study does not qualify under exemption category– please see the** [Expedited review](http://research.umbc.edu/expedited-review-process/) procedures**)**

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[ ]  **Category 2 [(§46.104(d)(2)]:** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including video or audio recording) ***if at least one of the following criteria*** is met:

[ ]  **2(i)** -The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

[ ]  **2(ii)** - Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation;

1. Does the research involve minor participants?

[ ]  **Yes** [ ]  No

1. If yes, does the research involve surveys?

[ ]  **Yes** [ ]  No

If **yes**, to a) and b), **Exemption Category 2(i) or 2(ii)** does not apply- please see the [Expedited review](http://research.umbc.edu/expedited-review-process/) procedures.

[ ]  **2(iii)** - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a **limited IRB review** required by (§46.104.111(a)(7) to protect privacy and confidentiality. ***This category may NOT be applied to research with children.***

1. Does the research involve an *intervention*? [ ]  **Yes** [ ]  No

An i*ntervention* is defined as, “manipulations of the subject or the subject’s environment that are performed for research purposes.” If **yes**, exemption category 2 does not apply- please see the [Expedited review](http://research.umbc.edu/expedited-review-process/) procedures.

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[ ]  **Category [(§46.104(d)(3)]:** Research involving benign behavioral interventions***1*** in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and ***at least one of the following criteria*** is met:

[ ]  A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects ***cannot readily be ascertained***, directly or through identifiers linked to the subjects;

[ ]  (B) Any disclosure of the human subjects' responses outside the research ***would not reasonably place the subjects at risk*** of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

***1*** - Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Examples of benign behavioral interventions include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

1. Describe the benign behavioral intervention:

Click here to enter text.

1. Does the research involve minors? [ ]  **Yes** [ ]  No

If the research will involve minors, the exemption does not apply- please see the [Expedited review](http://research.umbc.edu/expedited-review-process/) procedures.

If the research involves *deception* regarding the nature or purposes of the research, this exemption **is not applicable unless the subject authorizes the deception** through a prospective agreement to participate in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

1. Does the research involve deception? [ ]  **Yes** [ ]  No
2. If so, will subjects prospectively agree to be unaware of or misled regarding the nature of the research? [ ]  Yes [ ]  **No**

If **yes** to b) and c), the exemption does not apply- please see the [Expedited review](http://research.umbc.edu/expedited-review-process/) procedures.

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[ ]  **Category [(§46.104(d)(6)]:** Taste and food quality evaluation and consumer acceptance studies:

[ ]  (i) If wholesome foods without additives are consumed,

Or

[ ]  (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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**PARTICIPANT INFORMATION, RECRUITMENT, PRIVACY AND CONSENT**

**Describe the inclusion or exclusion criteria for participants as applicable in this study.**

Click here to enter text.

**Please indicate the estimated number of participants you plan to recruit, the age range of the participants, the tools that you plan to use to recruit your participants, and an estimate of the time commitment from each participant for each phase of the study:**

Click here to enter text.

**Will participants be compensated for their participation? If yes, what is the amount? What compensation is offered (e.g., money, gift cards, extra credit)? How will you track payments?**

Click here to enter text.

**Describe the consent process. Explain who will obtain consent, when and where consent will be obtained (e.g., consent discussion in a private room)**:

Click here to enter text.

**Please indicate the informed consent process(es) and/or document(s) to be used in the study.**

**Check all that apply. Provide copies of documents, as applicable.**

[ ]  Adult Informed Consent – oral script/online/unsigned

[ ]  Assent (participants under 18) – oral script/online/unsigned

[ ]  Parental Permission – oral script/online/unsigned

[ ]  Translated Consent/Assent – form(s), script(s), etc. Other – please explain below

**Describe any potential risks, including physical, psychological, social economic, monetary, reputational, legal or other potential risks.**

Click here to enter text.

**What format(s) will the data originate (e.g. paper, digital, electronic media, video, audio or photographic)?**

Click here to enter text.

**Describe how data or study records will be kept confidential or explain how anonymity, privacy and/or confidentiality will be maintained.**

Click here to enter text.

**Will any data contain personal identifiable information (PII) (e.g., names, addresses, student/employee IDs, IP addresses, photos, or audio/video recordings)?**

Click here to enter text.

**Describe the safeguards to be implemented for protecting participant information and minimizing risks (e.g. password protections, coding systems, file encryption, etc.)?**

Click here to enter text.

**How long with collected data be kept?**

Click here to enter text.

**How will data be shared with research team members and/or collaborators?**

Click here to enter text.

**Will the collection / storage or data lead to a deductive disclosure of participant identifiers? If so, how will privacy be addressed?**

Click here to enter text.

**Please describe at what point in time will PII and/or deductive identifiers will be removed from the dataset and/or the records retention plan for the research records.**

Click here to enter text.