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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| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

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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| 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. |

**\* 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 (choose 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 involving secondary research where informed consent *is not* required.**

**PROJECT INFORMATION**

**Anticipated Duration of Study:**

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

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

Click here to enter text.

**What is the source of the private information or biospecimens (e.g., data, documents, medical records, academic records, human biological samples or specimens)? NOTE: for medical records, HIPAA rules apply; academic records, FERPA rules apply; biological samples or specimens require IBC review:**

Click here to enter text.

**Describe what private information or biospecimens will be obtained or recorded. For data, include a list of field names or variables, the date range of the files/records, the number of records, etc. For identifiable biospecimens, include a description of codes or potential identifiers, the type(s) of biospecimens utilized.**

Click here to enter text.

**Will you be collectingsensitive information? If so, you will be required investigators to follow**

**appropriate security protocols according to UMBC’s**[**Data Use Guidelines.**](https://docs.google.com/a/umbc.edu/document/d/1Yj49OMeHHQEj_gazOumzVPbsjE5hGa6m82RFBSG5H_8/edit)**The UMBC**

**Department of Information Technology (DoIT) may be brought in to prepare a risk**

**assessment documents and/or perform an onsite inspection of your data access and storage facilities. Review the** [**levels of security**](http://research.umbc.edu/special-topics-related-to-human-research-use-2/umbc-security-requirements-for-protecting-sensitive-research-data-guidelines-for-reporting-sensitive-information/) **that may require data protections. Provide information on encryption techniques, data access, etc. and describe below:**

Click here to enter text.

**REVIEW CATEGORIES**

Depending on the specifics of the project, the study can be eligible for review as one of the below. Please review and choose the appropriate category. Then, continue with the remainder of the application to explain the proposed study.

**=======================================================================**

[ ]  **Exemption Category [(§46.104(d)(4)]:** Secondary research for which consent is not required.

Secondary research uses of identifiable private information or identifiable biospecimens, if ***at least one of***

***the following criteria*** is met:

[ ]  i. The identifiable private information or identifiable biospecimens are publicly available;

Describe the publicly available source of the data and how one gains access to the data or specimens. Include any information on whether permission is required to access the data, or any Terms of Use that apply. For examples of publicly available data sources, see the [IRBs latest list.](https://research.umbc.edu/special-topics-related-to-human-research-use-2/use-of-pre-existing-data/)

Click here to enter text.

[ ]  ii. Information, which may include information about biospecimens, 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, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

Describe how the information or specimens will be recorded so that the identities of the human subjects may not be readily ascertained.

Click here to enter text.

[ ]  iii. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under HIPAA, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b);

Click here to enter text.

**UMBC is NOT a HIPAA Covered Entity, therefore this exemption category may NOT be used unless the research will take place at a covered entity and that entity determines through their IRB procedures that the exemption applies or UMBC formally enters into a Business Associate Agreement with the HIPAA Covered Entity.** Attach documentation that HIPAA Authorization for the release of information was obtained OR documentation from the Covered Entity’s Privacy Officer that a waiver of authorization was granted by the Privacy Board.

[ ]  iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with **specified privacy standards**.

 Please provide the name of the Federal department or agency for which the research is being conducted and describe which privacy standards apply

Click here to enter text.

**=======================================================================**

[ ]  **Expedited Category # 5:**  Research involving materials (data, documents, records, or specimens) that ***have been collected, or will be collected solely for nonresearch*** purposes (such as medical treatment or diagnosis).This category applies if information or biospecimens are not publicly available, AND codes or links to identifiers will be maintained (even temporarily) by the research team.

**=======================================================================**

**DATA SOURCE INFORMATION, PRIVACY AND CONFIDENTIALITY**

**What is/was the primary or initial purpose of data/biospecimen collection?**

Click here to enter text.

**Who is the owner of the data, records or biospecimens?**

Click here to enter text.

**How will the data from the owner to the investigator?**

Click here to enter text.

**Regarding the use of private information or biospecimens, what were research participants told regarding the use and confidentiality of their original information or specimen(s)? Attach original consent form or letter, as applicable*. If proposed secondary use is inconsistent with the original agreement, the IRB may require investigators to seek permission for the secondary use from participants.***

**Are the materials available to the general public for un-restricted use?**

[ ]  **Yes – describe how the information or biospecimens may be accessed by the public.**

Click here to enter text.

[ ]  **No - attach documented permission from the owner of the materials, HIPAA Privacy officer, and/or the responsible IRB allowing use in this research project. The permission should also describe any data use restrictions or provisions, and whether or not written authorization was obtained for release of the records.**

The investigator is also required to submit a **Data Use Agreement (DUA).** A DUA addresses university issues such as limitations on use of the data, liability for harm arising from the use of the data, publication, and privacy rights that are associated with transfers of confidential or protected data. The Office of Sponsored Programs (OSP) serves as the campus signatory for [**research-based Data Use Agreements.**](http://research.umbc.edu/data-use-agreements/) OSP is authorized to enter into contractual agreements, including DUAs, on behalf of UMBC to ensure compliance with appropriate policies and regulations.

**How will the data/material be obtained, transferred, and stored for the project?**

Click here to enter text.

**Describe the coding system that will be used to protect against disclosure of identifiers, if any.**

Click here to enter text.

**How long will any links between identifiers and code be maintained?**

Click here to enter text.

 **Could any disclosure of the participant’s responses place the participant at risk of criminal or civil liability or could the disclosure be damaging to the participant’s financial standing, employability, or reputation?**

Click here to enter text.

**When accessing medical records, will any of** [**HIPAA Identifiers**](https://privacyruleandresearch.nih.gov/pr_08.asp) **be obtained or recorded (e.g., names, geographic subdivisions, telephone numbers, fax numbers, email addresses, social security numbers, medical record numbers, web URLs , IP addresses, biometric identifiers including finger and voice prints, full face photographs, any other unique identifying number, characteristic, or code)?**

Click here to enter text.

To access PHI for research purposes, please complete and submit an [**HIPAA authorization to use and/or disclose PHI**](http://research.umbc.edu/files/2016/03/hipaaauthorization.docx) and include with your submission. In [some situations](https://research.umbc.edu/special-topics-related-to-human-research-use-2/hipaa/), the IRB can waive the requirement that research subjects sign such an authorization, particularly for use retrospective records review where the data are already collected. Please complete and submit a [**Waiver of HIPAA Authorization Form**](http://research.umbc.edu/files/2016/03/hipaawaiver.docx)withyour application.