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** | **Project Dates** | **Proposal or Award ID** |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
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Federal regulations [45 CFR 46.103(f](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.103))) require that investigators ensure the research described in the grant proposal application be consistent with any corresponding protocol(s) reviewed and approved by the IRB. Please attach a copy of the components of grant applications and contract proposals related to human subjects use [e.g. the Human Subjects section]

List the Principal Investigator(s) below. Please list other research team personnel on Page 3 of this application**.** Students may be listed as an Investigator; faculty advisors must also be shown and sign this form. ***Attach an abridged vita or resume*** to this application highlighting expertise of the Principal Investigator(s) as it relates to this study.

| Name | Department | Phone Number | E-mail | Date CITI Education Program was completed \* |
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**\* If you need information about training completion dates, please contact the ORPC**

***CITI Training Note:*** *All UMBC investigators, staff and research team members must use their* ***UMBC user credentials*** *(email address) to log into CITI using UMBC’s*[*Single Sign On (SSO) login*](https://www.citiprogram.org/index.cfm?pageID=668)*. New users will create a* [*new account in CITI*](https://about.citiprogram.org/en/homepage/) *and will be prompted to complete the required profile information. Returning users can login* [*into CITI*](https://about.citiprogram.org/en/homepage/) *using their current UMBC email address. Users who are missing current training record information may likely have multiple accounts (using different email addresses). Click on* [*this link to*](http://research.umbc.edu/education-training/) *learn how to merge these accounts to your current UMBC email.*

Does the Principal 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 [UMBC Conflict of Interest policies](http://research.umbc.edu/umbc-conflict-of-interest-forms-policies-procedures/)?

Yes  No  If you have any questions, please [contact the ORPC](mailto:compliance@umbc.edu).

Type of Review Requested:

Expedited - check the appropriate box at the end of this application

Full Board  - complete the necessary information on Page 7 of this application

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

***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. 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 during the term of IRB approval.***

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.

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

**IRB Action**: ***Expedited*** \_\_\_\_\_\_\_ ***Full Board Review*** \_\_\_\_\_\_\_\_

Approved - IRB Chair ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(application for approval of use human participants form) –07.31.2018

**1) Anticipated start date of the research:** Click here to enter a date.

**Approximately how long will it take to complete the research objectives (months/years):** Click here to enter text.

**2) List all other personnel who are working on this study**

| **Name** | **Role** | **Department** | **Phone Number** | **E-mail** | **Date CITI Education Program was completed** |
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**Role: Faculty Advisor (FA) , Research Assistant (RA), Graduate Student (GS), Undergraduate Student(US)**

***CITI Training Note:*** *All UMBC investigators, staff and research team members must use their* ***UMBC user credentials*** *(email address) to log into CITI using UMBC’s*[*Single Sign On (SSO) login*](https://www.citiprogram.org/index.cfm?pageID=668)*. New users will create a* [*new account in CITI*](https://about.citiprogram.org/en/homepage/) *and will be prompted to complete the required profile information. Returning users can login* [*into CITI*](https://about.citiprogram.org/en/homepage/) *using their current UMBC email address. Users who are missing current training record information may likely have multiple accounts (using different email addresses). Click on* [*this link to*](http://research.umbc.edu/education-training/) *learn how to merge these accounts to your current UMBC email.*

Will the procedures in this application be used for thesis, masters or dissertation research? Yes  No

If yes, please list thesis or dissertation committee member names: Click here to enter text.

Planned graduation date?Click here to enter a date.

**3) Purpose of the Study:** What are the specific scientific objectives (aims) of the research?

Please attach additional information to this application (i.e. specific aims, project description,

etc.) if you wish to provide additional information about the protocol.

Click here to enter text.

**4) Procedures**: Describe the all procedures of the study in which human participants will participate.

**Please include Microsoft Word versions of recruitment fliers. Adobe Acrobat (.pdf) versions of**

**questionnaires, surveys or other measures related to the proposed project are acceptable**.

Please describe if he proposed project will involve the active collection of data from participants, the

active collection and use of human biological materials or physiological data, the use of existing data

(not human biological materials) or the use of existing human biological materials. When using multiple

questionnaires, surveys or other measures, describe which questionnaires, surveys or other measures will

be used for specific procedures.

Click here to enter text.

**5) Participant selection:** Who will be the participants? Examples include adult volunteers, children

under 18, UMBC students or employees, cognitively impaired persons, people in or from foreign

countries, persons unable to read, speak or understand English, or those with limited literacy, etc.

**Please explain:** How and from where will they be obtained? What are the criteria for inclusion and

exclusion? What is the estimated number of participants and age range? How will eligibility be

determined, and by whom? Will the participants be selected for any specific characteristics, e.g., age,

sex, race, ethnic origin, religion, or any social or economic qualifications?

Click here to enter text.

**6) Process of Consent:**  How and where will the consent process take place? Who, among the research

team members, will obtain consent? What information will be provided to participants if a research

study deals with anonymous research, recording instruments or reportable activities (e.g. illegal drug

use, child abuse, etc.) What steps will be taken to avoid coercion or undue influence? Describe the

process here and make sure the process is consistent with description in the consent or assent forms. If

not obtaining written consent (with submission of a waiver of written consent requrest), how will

consent conversations be documented (consent log, spreadsheet, etc.)? Please include with the

application.

**Please include Microsoft Word versions of all consent and assent documents or consent scripts.**

Click here to enter text.

Which consent documents are attached to this application?:

Adult Consent Form  Child Assent Form Waiver of Written Consent

Oral Consent Script  Telephone Consent Script  Information Sheet  Email Consent Document

Parent/Guardian Consent Form  Web-based Consent Form

**7) Data Collection, Storage and Confidentiality:** How will data be collected and recorded?

Will it be associated with personal identifiers or coded to protect personal privacy?

Who will have access to the data and/or to the codes? If data with participant identifiers, who

will have or maintain access to this information?If providing payments to participants how will

these payments be tracked and identifying information kept secure? If a participant decides to

withdraw from this study, what procedures will you use to protect the confidentiality of the data

during your analysis? Provide a location where data records or information will be stored or

available. Where will data and associated protocol files reside upon completion of the study?

Will be use a computer, laptop, tablet or smartphone to collect data?

Click here to enter text.

***Confidentiality of collection of sensitive information*** may require 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)  Review the [levels of](http://research.umbc.edu/special-topics-related-to-human-research-use-2/" \l "sensitive)

[security](http://research.umbc.edu/special-topics-related-to-human-research-use-2/" \l "sensitive) that may require data protcections. The UMBC Department of Information Technology

(DoIT) may be brought in to prepare a risk assessment documents and/or perform an onsite

inspection of the PIs’ data access and storage facilities. You may be required to provide

information on encryption techniques, data access, etc. If so, it ***must be*** detailed in the IRB

protocol application for review.

Click here to enter text.

**8) Research that use data, records or human biological specimens *with* direct participant contact**

**(complete if applicable):**

What procedures will you and the research team put into place to minimize or eliminate exposure

to potentially infectious agents that may be present in the specimens (i.e. human blood, tissues or

body fluids)? Describe your plan for exposure control and personnel protection.

Click here to enter text.

Will the activities of this research fall under the HIPAA Privacy Rule? Yes  No

If “Yes,” describe the procedures you will use to comply with the HIPAA Privacy Rule Click here to enter text.

**9) Research that use data, records or human biological specimens *without* direct participant**

**contact (complete if applicable):**

**What are the types of data or specimens? (See** [**OHRP guidance**](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/)**)**

Private information or specimens not individually identifiable and not be linked to specific

individuals by the investigator(s) either directly or indirectly through coding systems.

Identifiable private information or specimens already collected and provided to investigator for a research study

Identifiable private information or specimens already in the possession of the investigator

Medical records

Patient specimens (tissues, blood, serum, surgical discards, etc.)

Other (specify): Click here to enter text.

**Note: if data or specimens** are **existing** at the time the research (collected prior to the current project) or information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers, [exempt review](http://research.umbc.edu/exempt-application-process/) may apply. Contact the [OPRC](mailto:compliance@umbc.edu) for guidance.

**What is the source of the data or specimens and how were they collected? Describe the process of data collection including consent, if applicable**. Click here to enter text.

**Are the data or specimens publicly available? (That is, can the general public obtain the data or specimens? Data are not considered publicly available if access is limited to researchers.)**

Click here to enter text.

**If the data or specimens are not publicly available, please attach permission from the data owner to use the data for the purpose defined in the protocol.**

Yes  No

Note: Access to specific types of data require full consideration and permissions to share such information, as well as regulatory compliance regarding its use and security. The IRB may provide conditional approval of a protocol if it is needed in order to obtain a [Data Use Agreement](http://research.umbc.edu/files/2015/07/DUA_Submission_Form_082313.doc) signed, but final approval will not be granted until a copy of the signed Data Use Agreement is received from OSP with required security measures in place.

**Will the data or specimens obtained for this study remain identifiable in the research records?** Yes  No

**What confidentiality measures will you put into place to protect identities?** Click here to enter text.

Data holders whose archives are available on a restricted basis have certain conditions for use and possession. Investigators ( the “data users”) must be aware of these provisions as their research must conform with confidentiality and data protection provisions of the [Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)](http://www.glin.gov/download.action?fulltextId=168374&documentId=83278&glinID=83278), the [Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule](http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html) and/or the [Family Educational Rights and Privacy Act (FERPA)](http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html). Each of these regulations obligates “data users” to protect the privacy and confidentiality of personal identifiable information that they possess and to obtain permission, when warranted, from individuals to disclose information. Users may also be audited by federal agencies to make sure they are following proper procedures. Penalties for non-compliance with these regulations include financial fines are/or imprisonment.

**What procedures will you and the research team put into place to minimize or eliminate exposure to potentially infectious agents that may be present in the specimens (i.e. human blood, tissues or body fluids)?**

Describe your plan for exposure control and personnel protection. Click here to enter text.

**10) Risks/Benefits:** What potential benefits may participants receive as a result of their participation in

the research? What are the potential risks/discomforts associated with each intervention or research

procedure? What procedure(s) will be utilized to prevent/minimize any potential risks or discomfort?

Click here to enter text.

**11) Location:** Where will the study be conducted (e.g. institutions, organizations, facilities such schools,

churches, child centers, businesses, nursing homes, conferences, etc.). Is local or institutional IRB

approval from the recruitment/research site required? If so, please include a copy with the application.

Letters of cooperation from sites that generally consist of a broad statement indicating that the

researcher will be allowed to recruiting participants, conduct his or her study procedures and collecting

data at a specific facility are not considered human subjects use approval but may be submitted as part of

the application.

Click here to enter text.

**COMPLETE ONLY FOR MORE THAN MINIMAL RISKS STUDIES**

**A) Background:** Please provide an evaluative summary of relevant literature on the topic **if** your protocol falls within the "**More than Minimal Risk** “category:(defined as: *"where the probability and magnitude of harm or discomfort anticipated in the proposed research are greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or test". [45 CFR 46.102(i)]*,)"

Click here to enter text.

**a.**. Ifadverse effects occurred, indicate how your research is addressing or attempting to prevent such effects. Include full citations for included research. If possible, also include a copy of relevant articles.

Click here to enter text.

**b.** For **More than Minimal Risk** studies that ALSO include invasive procedures, indicate which databases have been consulted (e.g., Medline). Summarize findings, including findings of adverse effects and steps taken by you to prevent this from occurring in your protocol. You may reference your response in 3a, as appropriate.

Click here to enter text.

**B)**  **Independent reviewers**: If your protocol is ***More than Minimal Risk***, please list the names

And contact information (telephone, e-mail, address) of 3 experts in your field who can independently

evaluate your proposal and assist the IRB in the review process.

Click here to enter text.

**Protocol Application checklist**

A one-paragraph abstract describing the protocol

Copy of IRB approval from collaborative institutions

Investigator(s) vita

Consent documents

Questionnaires, measures, survey instruments

Advertisements/recruitment letters

**Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure**

**Please check the category that applies**

| **1)** Clinical studies of drugs and medical devices only when condition (a) or (b) is met.  (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)  (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. | **2)**  Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:  (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or  (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. |
| --- | --- |
| **3)** Prospective collection of biological specimens for research purposes by noninvasive means.  Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtainedat the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization. | **4)** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited  review, including studies of cleared medical devices for new indications.)  Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. |
| **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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.) | **6)** Collection of data from voice, video, digital, or image recordings made for research purposes. |
| **7)** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.) |  |