`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** |
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List the project personnel below. ***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 \* | Describe role in the project |
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**\* If you need information about training completion dates, please contact the ORPC**

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’s Conflict of Interest policies?](http://research.umbc.edu/conflicts-of-interest-and-commitment/)

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

Type of Review Requested:

Expedited Category Research

Full Board Research – complete this application and the necessary information on last page of this application

**Electronically submit the protocol and any accompanying documents to** [**irbsubmissions@umbc.edu**](file:///C:\Users\sparklin\AppData\Local\Box\HARPO\IRB\irb%20forms\irbsubmissions@umbc.edu)**.**

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***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 concernsduring the term of IRB approval***

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**For more information, review the Office of Human Research Protections**

[**Categories of Research under Expedited Review**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html)

**Please check the category that applies to your research**

| **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. |
| **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.) | **NOTE: Continuing review is *no longer required* for research that has progressed to the point where:**   * the project was initially eligible and continues to be eligible for expedited review procedures; * the research is permanently closed to the enrollment of new participants, all participants have completed all research-related interventions, and the research remains active only for long-term follow-up of participants; * project personnel have enrolled no participants and no additional risks have been identified; * the research has progressed to data analysis, including analysis of identifiable private information or identifiable biospecimens |

**1) Anticipated Duration of Study:** From (Date) Click here to enter a date.

End (Date) Click here to enter a date.

When planning the study, take into account how long the project will take. Final IRB approval will take these dates into account

**2) List all other personnel who are working on this study (continued from Page 1)**

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

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.

**3) Purpose of the Study:**

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

Click here to enter text.

**4) Procedures**:

Describe the **ALL** procedures proposed for the study. Then, choose the appropriate checkboxes below

relate to your procedures. Inlcude details such as: 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? When using multiple questionnaires, surveys or other measures, describe which questionnaires, surveys or other measures will be used for specific procedures. Provide an estimate of the time commitment from each participant for each phase of the study.

Click here to enter text.

Select **ALL** the methods of data collection that will be employed in this study (select all that

apply)

In person interviews

Paper surveys

Telephone surveys

Internet surveys (including online and email based data collection)

Use of Social Networking Sites (e.g., Facebook, Instagram, etc.)

Data collected using other communication/electronic devices (e.g., cell phones, pagers and texting

devices)

Observation

Cognitive or behavioral measures, including daily diaries

Focus groups

Audio/Video recording

Anthropometric measures (e.g., height, weight, waist circumference, etc.)

Self health monitoring (e.g., pedometers, food diaries, etc.)

Other activities or interventions

Click here to enter text.

Select **ALL** the specific locations where data will be collected (select all that apply)

Participants’ homes

Elementary, secondary or high school – specify where Click here to enter text.

UMBC campus– specify where Click here to enter text.

Other university campuses – specify where Click here to enter text.

Hospitals– specify where Click here to enter text.

Nursing homes, assisted living, residential communities– specify where Click here to enter text.

Other (Please describe below)

Click here to enter text.

Select **ALL** of the tools that you plan to use to recruit your participants and include with your

application.

Flyers

Notices

Mailers (U.S. Postal Service)

Online Advertisements

Email

Use of Internet social media or online networking sites

TV, radio, print advertisements

UMBC participant pool recruiting methods (such as Sona Systems)

Face to face public meetings

Presentations at meetings

Other (Please describe below)

Click here to enter text.

**Please include Microsoft Word versions of recruitment fliers. Word and Adobe Acrobat (.pdf) versions of questionnaires, instruments, surveys or other measures related to the proposed project are also acceptable.**

**5) Location:**

Describe where the study will 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.

**6) Participant selection:**

Explain how and from where will they be selected. By choosing the categories below, what are the

inclusion or exclusion criteria? 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, social

or economic qualifications, unable to read, speak or understand English, or those with limited literacy,

etc. Indicate the estimated number of participants you plan to recruit

Click here to enter text.

Select **ALL** the categories of participants that will be included in your study.

Healthy adult volunteers

Children under 18

UMBC students

UMBCemployees

Cognitively impaired persons

People in or from foreign countries

Other (Please describe below)

Click here to enter text.

**7) Process of Consent:**

How and where will the consent process take place? Note that consent documents must contatin “key

information” essential to decision making; these details must appearat the beginning of the consent

form and being presented first in the consent discussion. 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.

Click here to enter text.

Remember it is the responsibility of the investigator to:

* Provide more information when requested by subjects
* Make sufficient time and opportunity to discuss the research
* Answer questions to improve a subject’s understanding

Indicate the informed consent process(es) and/or document(s) to be used in the study. Provide copies of documents, as applicable.

Adult Informed Consent

Minor/Child Assent (participants under 18)

Cognitive Impairments and Decision-Making Capacity Assent

Parent / Guardian / LAR Consent

Translated Consent/Assent –form(s), script(s), etc.

Debriefing script

Other (Please describe below)

Click here to enter text.

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

**Waivers of Informed Consent**

Informed consent is more of a conversation process, rather than a means for obtaining a signature.  Occasionally there are reasons to waive written consent or to alter the requirements of consent. Researchers are required to inform participants in written or verbal form of the primary purpose of the research project and of any procedures which they will undergo. Under certain circumstances, the use of written consent documents may be waived or alteration of the consent process may be approved. An investigator may request a waiver, but it **must be** justified for its use. The IRB will take into consideration the risks and potential harms involved in these requests to approve.

Choose the appropriate [waiver of consent document](https://research.umbc.edu/waivers-of-informed-consent/). The justification for waviers of consent from these documents MUST also be included in this section of the application. Describe how will consent conversations be documented (consent log, spreadsheet, etc.)? Electronic consent is allowed, but participants must be provided a written copy (available via mail, email or instructions to download from a website, etc.).

Click here to enter text.

**8) Data Collection, Storage and Confidentiality:**

How will data be collected and recorded? 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 compensation 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 the 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.

**9) 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, including physical, psychological, social economic, monetary, reputational, legal or other potential risks? What procedure(s) will be utilized to prevent/minimize any potential risks or discomfort?

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

**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.