**Research Title:** Click or tap here to enter text.

**Principal Investigator Information:**

**Name:** Click or tap here to enter text.

**Email:** Click or tap here to enter text.

**Institution:** Click or tap here to enter text.

**Is the principal investigator a current employee of Prince George’s Community College?  Yes  No**

**Source of Funding (if any):** Click or tap here to enter text.

**Proposed Start Date:** Click or tap to enter a date.

**Type of Review Requested\*:  Exempt  Expedited  Full Review**

**\*Examples of research that falls under each type can be found in the PGCC IRB Procedures document. Please check the appropriate box for the specific research category at the end of the application.**

**Will the procedures in this application be used for thesis, masters or dissertation research?**

**Yes  No**

***By typing your name and date, the investigator certifies they will abide by all PGCC 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 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 or tap here to enter text. **Date:** Click or tap to enter a date.

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

**(if applicable)**

1. **Purpose of the research:** What are the specific scientific objectives (aims) of the research? Please include empirical research that informs the rationale for this study (including rationale for proposed population), how the current study will contribute to the scientific literature, and definitions for any terms specific to your area of study.

Click or tap here to enter text.

1. **Research procedures:** Describe all procedures of the study. This includes, but is not limited to, the timeline of research tasks (each step of recruitment and participant tasks), a detailed description of the research design (correlational, survey, random assignment procedures, qualitative, etc.), description of measures used, how responses will be recorded, an overview of the data analysis plan, how participants will be contacted throughout the study, and the setting/location of research tasks.

Click or tap here to enter text.

1. **Participant recruitment and selection process:** Who will be the participants and how will they be recruited? Please explain how and from where they will be recruited, method of initial contact, the criteria for inclusion and exclusion (e.g., age, sex, race, ethnic origin, religion, social or economic qualifications, enrollment characteristics, etc.), the estimated number of participants and age range, and how eligibility will be determined and by whom.

Click or tap here to enter text.

1. **Process of consent:** Describe the process you will use to obtain informed consent (how and where the consent process will take place, how participants will submit consent forms, if not obtaining written consent—with submission of a waiver of written consent request—how consent conversations will be documented (e.g., consent log, spreadsheet), etc.), and provide your consent form within this application (Consent Form Template included below).

Click or tap here to enter text.

1. **Data collection, storage, and confidentiality:** How will data be collected and recorded? Will it be associated with personal identifiers, coded to protect personal privacy, or completely anonymous? 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? 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 you use a computer, laptop, tablet or smartphone to collect data? How long will the data be kept, and how will you ensure confidentiality when materials are destroyed?

Click or tap here to enter text.

1. **What are the potential benefits of participation in this research (e.g., directly to the participants, Prince George’s Community College, populations that may be positively impacted by this research, etc.)?**

Click or tap here to enter text.

1. **What are the anticipated risks/discomforts of participation in this research?** Risks can be physical, psychological, or economic in nature. What steps will be taken to protect participants from these risks/discomforts?

Click or tap here to enter text.

* 1. **Would risks/discomforts in this research be classified as “less than minimal risk” or minimal risk?”**

**Less than minimal risk  Minimal risk  More than minimal risk**

**Minimal risk** occurs when the probability and magnitude of harm/discomfort are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Exemption Categories**

Certain broad categories of research projects that involve human participants may be [exempt from full IRB review](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.101) and may qualify for "exempt" review. The IRB reserves the right to deny exemption requests whenever risks are identified that go above "minimal" or there is a concern for the welfare of human subjects. If the research does not fit into one of the categories below, it will require expedited review.

Please review the Exempt Category Example Chart and check the category or categories below which describe your research:

| EDUCATIONAL RESEARCH: Research conducted in established or commonly accepted educational settings, involving normal educational practices. This is research that is concerned with improving educational practice and does not include variables traditionally investigated in clinical and counseling research (self-esteem, anxiety, aggression, withdrawal, shyness, social skills, etc.) | EDUCATIONAL TESTS: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. |
| --- | --- |
| SURVEYS, QUESTIONNAIRES, INTERVIEWS, OR OBSERVATION OF PUBLIC BEHAVIOR: To meet this exemption, the subject matter must not involve "sensitive" topics, such as criminal or sexual behavior, alcohol or drug use on the part of the participants, unless they are conducted in a manner that guarantees anonymity for the participants (such as in anonymous observations or questionnaires). | SURVEYS, QUESTIONNAIRES, INTERVIEWS OR OBSERVATION OF PUBLIC BEHAVIOR: Surveys that involve sensitive information and participants’ identities are known to the researcher may still be exempt if (1) the participants are elected or appointed public officials or candidates for public office; or (2) federal statute(s) specify without exception that confidentiality will be maintained throughout the research and thereafter. |
| ARCHIVAL RESEARCH: Research involving the collection or study of existing data, documents, or records, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants. These data/samples must be preexisting (i.e., they were collected prior to the current project). | TASTE EVALUATION RESEARCH: Studies of taste and food quality evaluation. Studies of taste evaluation qualify for this exemption only if (1) wholesome foods without additives are consumed; or (2) if a food is consumed that contains a food ingredient at or below the level of and for a use found to be safe. |

**Expedited Review Categories**

Please review the Expedited Category Example Chart and check the category or categories below which describe 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 is not required.  (b) Research on medical devices for which (i) an investigational device exemption application 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, non-pregnant adults who weigh at least 110 pounds. where 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, where 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 (e.g., hair and nail clippings in a non-disfiguring manner, excreta and external secretions (including sweat), mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings, sputum collected after saline mist nebulization). | **4)** Collection of data through non-invasive 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 (e.g., 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, weighing or testing sensory acuity, 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, or records) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis) that does not fit the criteria for exempt review. | **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 that does not fit the criteria for exempt review. |  |

**Consent Form**

**[Project Title:** *This is the title participants will see. This project title does not need to match exactly the title from your IRB application, as this may “give away” information that could skew results of the study.***]**

**Summary Description of Research Procedures**

*[Briefly describe what the participant will be expected to do in up to 150 words. Please use non-technical and non-academic language. The purpose of this section is to make it easier for participants to understand what they will be doing and give informed consent for participation.]*

**Purpose of Study**

*[Briefly describe the scientific purpose of the study in no more than 100 words. Please use non-technical and non-academic language. The purpose of this section is to give a general sense of the area of research. You do not need to include specific details that may “give away” too much information to the participant and skew your study results.]*

**Benefits/Potential Risks or Discomforts**

*[Describe any benefits and/or potential risks or discomfort for participation in this study –if there are none, please state that there are no benefits/risks for participation in the study. Up to 75 words. Please use non-technical and non-academic language.]*

**Confidentiality Information**

*[How will data be stored securely and confidentiality ensured? Up to 75 words.* *Please use non-technical and non-academic language.*]

**Voluntary Participation**

Participation in this research is voluntary. Declining to participate will in no way impact your relationship with *[Primary Investigator],* the *[XXX Department (if applicable)],* or Prince George’s Community College. If you decide to participate in the study, you have the right to withdraw at any time.

**Consent Statement**

***[CHOOSE ONE (Primary Investigator must choose EITHER statement A or B below, depending on which is more applicable to your research design. Statement A may be adapted for online survey distribution- if applicable, please include exact text from your survey consent statement):]***

|  |  |
| --- | --- |
| A | I understand the procedures described above. My questions have been answered to my satisfaction, I have been offered a copy of this consent, and I agree to participate in this study.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_  Print Name: Date  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Participant’s Signature |
| B | I understand the procedures described above and all questions have been answered to my satisfaction. By returning this [questionnaire, survey, etc.] I agree to participate in this study. |

*This project complies with the requirements for research involving human subjects by PGCC Research, Assessment, and Effectiveness. If you have any questions or concerns about being a participant in this project feel free to contact the Primary Investigator [Primary Investigator] by phone [999-999-9999] or by email [XXX@xxxxx.xxx] or the Executive Director of Research, Assessment, and Effectiveness at 301-546-0723.*

Application Materials Checklist

Required for all applications:

Completed application, including electronically-signed cover page

Consent document

Additional materials (if applicable):

Copy of IRB approval from home institution

Questionnaires, measures, survey instruments, etc. (Word document(s) and/or provide link to online instruments)

Advertisements/recruitment letters (Word document)

Letter of cooperation from sites other than Prince George’s Community College campus or extensions centers