

## Consent Agreement

This is a consent form requesting voluntary participation in a high school Science, Technology, Engineering, and Mathematics (STEM) project. Please read the following information about the project. If in agreement, print your full name, sign the document, and

### Project Title

*Integrating E-Textiles, Nanotechnology, and AI to Enhance Physiological Data Acquisition*

### Student Investigators

*Emma A. Simmons*

*Sarah C. Simmons*

### Purpose of the Project

This project tests a novel method of acquiring and measuring key physiological functions through the integration of advanced materials science, nanotechnology, electronics engineering, and artificial intelligence. The goal of the project is to design and fabricate a prototype that is low-cost, easily accessible, portable, and noninvasive.

  X   This project has received Mount St. Mary's University IRB approval.

### Subject Activities

1. Wear a shirt/vest containing small electronic sensors that do not come into direct contact with the human body. The prototype will detect and record basic physiological data.
2. Have basic physiological data recorded using commercial devices typically found in a home environment.
3. Subjects will perform several everyday types of activities, such as standing and walking while wearing the prototype garment.

### Potential Risks of Participating and Risk Mitigation

Student researchers will be monitored by the project's adult direct supervisor, a parent, a qualified scientist, and a licensed medical professional.

1. Skin allergies. The prototype is constructed of a cotton-nylon blend shirt, common electronics, and graphene. All materials are very low risk. However, student researchers may experience minor skin irritation if they contact the materials. To lessen these risks, Students may wear their own lightweight clothing under the prototype garment and will be provided with provided with non-latex gloves.
2. Slightly accelerated breathing. While the level of physical activity is no greater than and often less than what the student researchers experience during normal everyday activities, they may experience breathing that is slightly accelerated. To mitigate this risk, student researchers will be instructed that they may rest at any time.
3. Slipping or tripping. Because student researchers will be walking, they may slip or trip. To reduce this risk, all obstacles will be removed from the walking path. Student researchers will be asked to wear rubber-soled shoes.

### **Time Required for Participation**

Approximately 15 Minutes.

### **Research Benefits**

The overarching goal of this project is to explore how advancements in science and technology can be used to innovate new ways of collecting and measuring physiological functions that are lower cost and more accessible while retaining accuracy and reliability. Neither the biosensors nor the prototype is intended or should be used for diagnostic or any other medical purposes.

### **Confidentiality**

All data collected and the consent form will be kept confidential. Hard data will be stored in a locked cabinet in a secure location accessible only to the student researchers and the adult project supervisor. Digitized data will be password-protected, encrypted, and uploaded to a virtual private server (VPS) that does not have public access. Digital and hard data will be kept for 48 months after the last test is completed and then destroyed.

### **Voluntary Participation & Freedom to Withdraw or Refuse Participation**

Student researchers, who are under 18 years of age, voluntarily agree to participate in this project in order to test the functionality of the prototype that they developed. Parents/legal guardians of the student researchers consent to their children participating in this project in order to test the functionality of the prototype that their children developed. The student researchers and parents/legal guardians of the student researchers have the right to ask questions about the procedures and for these questions to be answered. They further have the right to refuse to participate, stop participating, and withdraw their consent at any time with no negative impacts or consequences.

### **Contact Information**

*Dr. Dana Ward, Mount St. Mary's University, Frederick, MD ([dward@msmary.edu](mailto:dward@msmary.edu))*

### **Informed Consent Statement**

*By signing this agreement, I am attesting that I have read and understand the information above, and I freely give my consent for my minor child to participate and have been notified that they can I or they can withdraw from the project at any time with no negative consequences.*

**Parent/Legal Guardian Print Name:** Dr. Lisa S. McLeod-Simmons

**Parent/Legal Guardian Signature:**  **Date (mm/dd/yyyy):** 11/01/2024

**Student Print Name:** Emma A. Simmons

**Student Signature:**  **Date (mm/dd/yyyy):** 11/01/2024

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**Parent/Legal Guardian Signature:**  **Date (mm/dd/yyyy):** 11/01/2024

**Student Print Name:** Sarah C. Simmons

**Student Signature:**  **Date (mm/dd/yyyy):** 11/01/2024