Test Up Now Education Program

NCT04304001

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Informed Consent Form

FAMU COLLEGE OF PHARMACY + PHARMACEUTICAL SCIENCES INSTITUTE OF PUBLIC HEALTH
FLORIDA AGRICULTURAL AND MECHANICAL UNIVERSITY

Participant ID #: _____

Test Up Now Education Program (TUNE-UP)
Verbal Informed Consent to Participate in Research at Florida A&M University
Information to Consider Before Taking Part in this Research Study

Researchers at Florida A&M University study many topics. To do this, we need the help of people who agree to take part in a research study. This form tells you about the research study.

We are asking you to take part in a research study that is called Test Up Now Education Program (TUNE-UP). The person in charge of this research study is **Dr. John Luque**. This person is called the Principal Investigator. Dr. Luque is Professor in the College of Pharmacy and Institute of Public Health at Florida A&M University. However, other research staff will be involved and can act on behalf of the Principal Investigator.

The person explaining the research to you may be someone other than the Principal Investigator. Other research personnel who you may be involved with include the Project Coordinator or Community Health Advisor. The study will take place in Leon and Gadsden County. The research is being paid for by the National Institutes of Health.

Why is this research being done?
This research study will test the effectiveness of a Community Health Advisor (CHA) educational intervention to increase colon cancer screening among African Americans in Leon and Gadsden County. In order to do this, we are testing how colon cancer education and the assistance of a CHA can help African American adults to receive colon cancer screening if they not up-to-date with screening.

What will happen during the study?
If you take part in this study, you will be asked to participate in a baseline survey and two follow-up surveys. The survey will ask questions about colon cancer screening, your health status, knowledge about colon cancer, and demographic information. All participants will receive an educational brochure and a home testing kit for colon cancer which they can mail in or hand deliver to the participating clinic following study participation. Some participants will be randomly selected to also receive education from a CHA either in person or over the phone.

To participate, you must be between 45 and 64 years of age, identify as African American, be a Florida resident, have a cell phone capable of sending and receiving text messages, and never been diagnosed with colorectal cancer, precancerous colorectal polyps, or inflammatory bowel disease. Also, participants are only eligible to

participate if they are not up-to-date with colon cancer screening meaning - no stool-based tests > 9 months, no colonoscopy within 9 years, and no flexible sigmoidoscopy within 4 years. Participation will take approximately 5 or 6 hours total for individuals participating in all the data collection activities.

Completion and return of the surveys implies your consent to participate in this research. Please keep this form for your records.

How many people will take part in this study?
Approximately 250 African American adults will participate in the study.

What other choices do you have if you do not participate?
You can choose not to participate in this research study. You may choose to review the educational materials without answering any questions about them.

What are the potential benefits if you take part in this study?
The potential benefits to you are:
1) Increased knowledge of cancer and specifically, colon cancer
2) Know where to receive colon cancer screening

What are the risks if you take part in this study?
There are no known risks to those who take part in this study, which is educational in nature.

Will you be paid for taking part in this study?
We will pay you for the time you volunteer to this study. A $20 stipend will be provided to each participant following the first survey and $30 stipend for the follow-up survey.

Please note: total payments within one calendar year that exceed $600 will require the University to report these payments to the IRS annually. This may require you to claim the compensation that you receive for participation in this study as taxable income.

Confidentiality
We must keep your study records as confidential as possible.

- Survey information, and these informed consent documents will be stored securely at Florida A&M University.
- Information will be held in password-protected computers and/or locked file cabinets.

However, certain people may need to see your study records. By law, anyone who looks at your records must keep them completely confidential. The only people who will be allowed to see these records are:

- The research team, including the Principal Investigator, co-investigators, research assistants, and all other research staff.
- There may be certain administrative personnel from Florida A&M University who may need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
- These include:
    - The Florida A&M University Institutional Review Board (IRB) and the staff that work for the IRB. Other individuals who work for Florida A&M University that provide other kinds of oversight may also need to look at your records.
    - Any federal, state, or local governmental agency that regulates the study.
    - The Department of Health and Human Services (DHHS).
    - People at the organization who paid for this study [The National Institutes of Health] may look at the study records and pertinent portions of your medical records to make sure the study is done in the right way.

We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are.

Where can you get the answers to your questions, concerns, or complaints?
Your participation in this research project is confidential and completely voluntary: you may choose not to answer any question and/or stop participating in the survey at any time.

If you have any questions about this project, please contact Dr. John Luque, john.luque@famu.edu, 850-561-2054.

Also, you can contact the IRB Chairperson below:
IRB Chairperson:
Dr. Angela Thornton, Florida A&M University, Institutional Review Board
Room 308H SR, Tallahassee, FL 32307-3800
Telephone: 850-412-5246

Florida A&M University
Institutional Review Board

Approved on:	**05/21/2022**
Expires on:	**05/21/2023**
Study number:	**049-19**
Questions or concerns IRB Office	**850-412-5246**

Statement of Person Obtaining Verbal Informed Consent

I have carefully explained the study and consent to the person as signed above. I have taken part in the consent process prior to the participant's consent and discussed in detail the study aims, methods, anticipated benefits, potential hazards or discomforts, and treatment alternatives. I have answered any and all questions the participant has asked. No study procedures were initiated prior to consent.

Signature of Person Obtaining Informed Consent Date

_____ ___/___/___

Participant ID # _____

Questions or concerns

Florida A&M University Institutional Review Board

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