THE UNIVERSITY OF ALABAMA®
Office of the Vice President for
Research & Economic Development
Office for Research Compliance

October 12, 2018

Amy C. Ellis, PhD, RD, LD
Assistant Professor
Department of Human Development & Family Studies
College of Human Environmental Sciences
The University of Alabama
Box 870311

Re: IRB Protocol # 16-001-ME-R2-A
"Bioactive Compounds in Watermelon Modulating Oxidative Stress and Inflammation in Elders: The MOXIE Study"

Dr. Ellis:

The University of Alabama Medical Institutional Review Board has reviewed the revision to your previously approved full board protocol. The board has approved the change in your protocol.

Please remember that your protocol will expire on January 10, 2019.

Should you need to submit any further correspondence regarding this proposal, please include the assigned IRB application number. Changes in this study cannot be initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to participants.

Good luck with your research.

Sincerely,

J. Grier Stewart, MD, FACP
Medical IRB Chair

IRB Project #: 16-001-ME -R2-A

UNIVERSITY OF ALABAMA
INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS
REQUEST FOR APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS

I. Identifying information

	Principal Investigator	Second Investigator	Third Investigator
Names:	Amy C Ellis	Kristi Crowe-White	
Department:	Human Nutrition and Hospitality Management	Human Nutrition and Hospitality Management	
College:	CHES	CHES	
University:	University of Alabama	University of Alabama	
Address:	412 Russell Hall, Box 870311	485 Russell Hall, Box 870311	
Telephone:	205-348-8128	205-348-6173	
FAX:	205-348-2982	205-348-2982	
E-mail:	aellis@ches.ua.edu	kcrowe@ches.ua.edu	

Title of Research Project: Bioactive Compounds in Watermelon Modulating Oxidative Stress and Inflammation in Elders: The MOXIE Study.

Date Submitted: 08-15-18
Funding Source: The American Heart Association

Type of Proposal	☐ New	☒ Revision	☐ Renewal Please attach a renewal application	☐ Completed	☐ Exempt
			Please attach a continuing review of studies form		
			Please enter the original IRB # at the top of the page		

UA faculty or staff member signature: Amy C Ellis

II. NOTIFICATION OF IRB ACTION (to be completed by IRB):
Type of Review: ___✓___ Full board _____ Expedited

IRB Action:
___ Rejected Date: _____
___ Tabled Pending Revisions Date: _____
___ Approved Pending Revisions Date: _____
✓ Approved-this proposal complies with University and federal regulations for the protection of human subjects.

Approval is effective until the following date: 1-10-19 e.s.
Items approved: ___ Research protocol (dated_____)
___ Informed consent (dated_____)
___ Recruitment materials (dated_____)
___ Other (dated_____)

Approval signature _____ Date 10/12/18

UNIVERSITY OF ALABAMA INSTITUTIONAL REVIEW BOARD

Informed Consent for a Medical or Health-Related Research Study

Study Title: Bioactive Compounds in Watermelon Modulating Oxidative Stress and Inflammation in Elders: The MOXIE Study.

Investigators: Dr. Amy Ellis, Assistant Professor, University of Alabama and Dr. Kristi Crowe-White Associate Professor, University of Alabama

Funding Source: The American Heart Association

You are being asked to take part in a research study. This study is called Bioactive Compounds in Watermelon Modulating Oxidative Stress and Inflammation in Elders: The MOXIE Study. The study is being done by Drs. Amy Ellis and Kristi Crowe-White, assistant professors at the University. This study is being paid for by a grant from The American Heart Association.

Does the researcher have any conflict of interest in this study?

The researchers do not have any conflicts of interest in this study.

What is this study about (or What are we trying to learn)?

This research study will test whether or not drinking100% watermelon juice for a four-week period can decrease stiffness of arteries and measures of oxidative stress. This study will enroll 34 women ages 55-69 years old.

What will I be asked to do in this study?

Screening:

To determine if you are eligible to participate in the study, the investigators must ask you a series of questions about your contact information, your medical history, and your current physical health. The purpose of these questions is to determine if you have any health-related problems that would exclude you from the study. Your height, weight, and blood pressure will also be measured at the screening visit, and you will be asked to complete two questionnaires about the foods you usually eat and the beverages you typically consume. Your screening visit will take approximately one hour.

Testing Procedures:

If you are eligible and interested in participating after the screening visit, you will randomly (like the flip of a coin) be assigned by a computer to a group receiving either 100% watermelon juice or placebo for a four-week period. After four weeks, there will be a two-week "washout" period when you don't consume

either beverage. After the two-week washout, you will consume the other beverage (either 100% watermelon juice or placebo) for another four-week period. Juice and placebo will be provided in two 12-ounce servings, and you will be asked to drink one dose in the morning and another in the evening with a meal. This will be a "blind study," which means that you will not know whether you have the 100% juice or placebo. However, if it becomes medically necessary for any reason, the blinding will be broken.

During this study, you will come to Russell Hall at UA once each week to pick up bottles of your beverages and have your body weight taken. You will also be provided with a calendar that has check-off boxes for you to record each time you drink the beverage.

At the beginning and end of each four-week period, you will come to the Russell Hall Building at UA for a testing visit. Each visit will take approximately two hours. At each of these four visits, researchers will gather the following information using the procedures described below:

24-hour diet recalls: Each week, someone from the study will ask you to recall the food and fluids you consumed the previous day. The first diet recall will be done in person, and all other recalls will be conducted over the telephone. Each recall may take about 20 minutes to complete. This information will be analyzed by a dietitian using a computer program to determine your eating patterns and nutrient intake.

Physical activity questionnaire: Four times during the study, you will complete a written questionnaire regarding both your recent and long-term physical activity levels. This questionnaire will take about 10 minutes to complete.

Questionnaires to assess motor speed and memory: Four times during the study, you will complete a short battery of questionnaires with a member of the study staff. These questionnaires resemble memory games, and they will take less than 20 minutes to complete.

Fasting blood sample: A fasting blood sample will be collected four times during the study in order to measure your blood levels of certain markers related to oxidative stress and artery stiffness. About 15 ml (or ~1 tablespoon) of blood will be collected at each blood draw.

Urine sample: To measure additional markers related to oxidative stress and artery stiffness, you will provide a urine sample at each testing visit.

Bioelectric Impedance Analysis (BIA): This test uses very mild electric current to estimate body composition. You will not be able to feel this current. The test involves placement of electrodes on your arms and legs using a sticky tape-like

material. A low-level electric current is passed through the body for approximately 5-10 seconds. The test takes approximately 10 minutes, including the time taken for positioning and electrode placement. This test will be done at each of the four testing visits.

Body measurements: Your body weight and height will be measured at each testing visit. Also, your waist circumference and several skinfold measurements will be taken using a tape measure and skinfold calipers. This will take about 10 minutes.

Flow Mediated Dilation (FMD): At each of the four testing visits, you will have an ultrasound of your arm to measure blood flow through your brachial artery. For this test, you will sit comfortably with your arm resting on a table. A blood pressure cuff will be placed on your forearm, and an ultrasound scanner will pass over your lower arm before and after the cuff is inflated. This test will take about 20 minutes.

Pulse wave analysis (PWA), Pulse Wave Velocity, and Continuous Ambulatory Blood Pressure: At each testing visit, you will be provided with a Mobil-O-Graph cuff to wear on your upper arm for the following 24 hours. This device will collect data about your blood pressure, and it will provide indexes of arterial stiffness based on measurement of the waveforms.

Blood pressure: At each of the four testing visits, blood pressure will be measured with a standard blood pressure cuff and automated monitor. This test takes approximately 5 minutes.

In addition, we are asking you to provide a one-time saliva sample for analysis of specific genetic markers that may help us understand how your body processes lycopene, a key ingredient of watermelon. Before you provide your saliva sample, you will be asked to refrain from eating, drinking, chewing gum, brushing your teeth, or using mouthwash for at least 30 minutes.

Collection of the saliva sample will take less than 5 minutes and includes the following steps:

- **You will be given a collection kit that consists of a disposable funnel and a small tube.**
- **You will be asked to spit a small amount (~ one teaspoon) of saliva into the funnel.**
- **A member of the research team will take the collection tube with your saliva.**

Your saliva samples will be destroyed after laboratory analysis of these specific genetic markers. Initial your choice below:

___ I agree to provide a saliva sample.

___ I do not agree to provide a saliva sample.

How much time will I spend being in this study?

- The screening visit will take approximately one hour.
- Each of the four testing visits will take approximately 2 hours. You will be asked to fast from food and beverages other than water for eight hours before each testing visit.
- Study staff will call you each week after your initial testing visit for a diet recall. Each of these calls will take approximately 20 minutes.
- Each week, you will come to Doster Hall at UA to be weighed and to pick up your bottles of beverage for the next week. These visits should take less than 10 minutes.
- The total estimated time commitment for this study including all screening visits, testing visits, and phone calls is approximately 13 hours.
- Collection of the saliva sample will take less than 5 minutes.

Will being in this study cost me anything?

There will be no cost to you for taking part in this study. The study will pay for the beverages and all study related assessments.

Will I be paid for being in this study?

You will receive $25 at each of the four testing sessions (total of $100). If you choose to withdraw from the study before completing all four testing sessions, compensation will be based on the number of sessions you completed until that point.

Can the researcher take me out of this study?

The researcher may take you out of this study if she feels that the treatment appears to be upsetting you or if something happens that means you no longer meet the study requirements.

What are the benefits (good things) that may happen to me if I am in this study?

You may not benefit directly from taking part in this study. However, this study may help us better understand how to improve blood vessel function through diet interventions in the future.

What are the risks (dangers or harm) to me if I am in this study?

- The juice used in this study is 100% watermelon juice that has been pasteurized. If you are allergic to watermelon, you should not participate in this study.

- The placebo beverage used in this study contains ingredients at or below levels found to be safe by the Food and Drug Administration and the U.S. Department of Agriculture.

- Taking blood from the arm vein may cause some minor pain at the site of the needle puncture, some bruising occasionally, rarely fainting. The cleansing of the site prior to puncture and the maintenance of sterile techniques will minimize the risk of infection.

- Some people may feel mild discomfort during the blood pressure cuff-inflation for FMD measurement. If you experience discomfort during this test, the measurement will be stopped.

- The manufacturer of the device that measures bioelectrical impedance recommends that it not be used on persons with implanted defibrillators or pacemakers. If you have a pacemaker or defibrillator, we will not perform this test on you, so be sure that you tell the researchers if you have a pacemaker or implanted defibrillator.

How will my privacy be protected?

The study staff will conduct all tests and interviews in a private room. You do not need to answer any questions you are uncomfortable answering.

How will my confidentiality be protected?

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UA Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including the Office for Human Research Protections (OHRP). The information from the research may be published for scientific purposes; however, your identity will not be given out.

What are the alternatives to being in this study? Do I have other choices?

All of the procedures in this study are for research purposes. The alternative to participation is to not participate in this study.

Storage of Specimens for Future Use

As part of this study, we would like to store some of the blood specimens collected from you for future research on lycopene and blood vessel function. The future research may be conducted by Dr. Amy Ellis, Dr. Kristi Crowe-White, or by other researchers who obtain IRB approval for their research. The specimens will be labeled with a code that only Drs. Ellis and Crowe-White can link back to you. Results of any future research will not be given to you or your doctor. The specimens obtained from you in this research may help in the development of a future diet studies. There are no plans to provide financial compensation to you should this occur.

You do not have to agree to allow your blood specimens to be stored in order to be part of this study.

You may request at any time that your research samples be removed from storage and not be used for future research. If you decide you want your samples removed, you may contact Dr. Amy Ellis at 205-348-8128. Once the request is received, and if your samples have not already been used for other research, they will be destroyed. If you do not make such a request, your specimens will be stored indefinitely or until used. Initial your choice below:

___ I agree to allow my samples to be kept and used for future research on hypertension.

___ I do not agree to allow my samples to be kept and used for future research.

What are my rights as a participant in this study?

Taking part in this study is voluntary—it is your free choice. You can refuse to be in the study. If you start the study, you can stop at any time. There will be no effects on your care or your relations with the University of Alabama.

The University of Alabama Institutional Review Board (IRB) is the committee that protects the rights of people in research studies. The IRB may review study records from time to time to be sure that people in research studies are being treated fairly and that the study is being carried out as planned.

Who do I call if I have questions or problems?

If you have questions, concerns, or complaints about the study right now, please ask them. If you have questions, concerns, or complaints about the study later on, please call the investigator (Dr. Amy Ellis) at (205-348-8128). If you have questions about your rights as a person taking part in a research study, you may call Ms. Tanta Myles, the Research Compliance Officer of the University at (205)-348-8461 or toll-free at 1-877-820-3066.

You may also ask questions, make suggestions, or file complaints and concerns through the IRB Outreach Website at http://ovpred.ua.edu/research-compliance/prco/. You may e-mail the Research Compliance Office at rscompliance@research.ua.edu.

After you participate, you are encouraged to complete the survey for research participants that is online at the outreach website or you may ask the investigator for a copy of it. Mail it back to the University of Alabama Office for Research Compliance, Box 870127, 358 Rose Administration Building, Tuscaloosa, AL 35487-0127.

I have read this consent form. I have had a chance to ask questions. I understand what I will be asked to do. I freely agree to take part in it. I will receive a copy of this consent form to keep.

_____ _____

Signature of Research Participant Date

_____ _____

Investigator Date

UNIVERSITY OF ALABAMA IRB
CONSENT FORM APPROVED: 10-12-18
EXPIRATION DATE: 10-10-19