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

August 10, 2017

Michael Fedewa, Ph.D.
Assistant Professor
Department of Kinesiology
College of Education
The University of Alabama
Box 870312

Re: IRB Protocol # 16-012-ME-R1
"Changes in HRV and Physical Activity during Exercise One Week of Exercise Training"

Dr. Fedewa:

The University of Alabama Medical IRB has received the revisions requested by the full board on 6/9/17. The board has reviewed the revisions and your protocol renewal application is now approved for a period of one year.

Your application will expire on June 7, 2018. You will receive a notice of the expiration date 90 days in advance. If your research will continue beyond this date, complete the renewal portions of the FORM: IRB Renewal Application. If you need to modify the study, please submit FORM: Modification of An Approved Protocol. Changes in this study cannot be initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to participants. When the study closes, please complete the FORM: Request for Study Closure.

Please use reproductions of the IRB approved stamped consent form or information sheet to obtain consent from your participants. Should you need to submit any further correspondence regarding this application, please include the above application number.

Please provide the Office for Research Compliance with copies of the approvals from the UA Radiation Control Advisory Committee and from the State of Alabama Department of Public Health for the IRB file prior to conducting any dual-energy x-ray absorptiometry (DXA) work associated with the current protocol.

Good luck with your research.

Sincerely,

J. Grier Stewart, MD, FACP
Medical IRB Chair

Research Study

Female students age 18 to 24 years are invited to participate in a one-week exercise training study examining the effect of structured exercise on physical activity.

All testing will be performed at Moore Hall at the University of Alabama.

Participants will be asked to complete confidential body composition analysis, as well as surveys regarding health history and physical activity. Participants can earn up to $10 with successful completion of the study.

If you are interested in participating, please contact the Principal Investigator: Michael V. Fedewa, Ph.D. (mvfedewa@ua.edu)

UNIVERSITY OF ALABAMA
INFORMED CONSENT DOCUMENT

Study Title:
Changes in HRV and Physical Activity During Exercise One Week of Exercise Training

Principal Investigator:
Dr. Michael V. Fedewa (205-348-9779; mvfedewa@ua.edu)
Assistant Professor, The University of Alabama

Co-Investigator:
Dr. Michael R. Esco (205-348-2151; mresco@ua.edu)
Assistant Professor, The University of Alabama

Student Co-Investigators:
Togy Bzagdsuren M.A. (bzagdsuren@crimson.ua.edu)
Doctoral Student

Peter Inglett M.A. (pwinglett@crimson.ua.edu)
Doctoral Student

You are being invited to participate in a research study. The study is called "Changes in HRV and Physical Activity During Exercise One Week of Exercise Training." The study is being done by Dr. Michael Fedewa and Dr. Michael Esco, who are assistant professors with the Department of Kinesiology at the University of Alabama. Our Doctoral Students, Togy Bazgdsuren and Peter Inglett will assist with the research study by obtaining informed consent and helping with data collection.

Is the study team being paid for this study? No, the researchers are not receiving extra pay for this study.

Is this research developing a product that will be sold, and if so, will the study team profit from it? No, the researchers are not developing a product that will be sold and will not directly profit from this study.

Does the study team have any conflict of interest in this study? The researchers do not have any potential conflicts of interest.

What is this study about? What is the study team trying to learn?
The purpose of this study is to determine if changes in your heart rhythm can be used to predict changes in physical activity during an exercise study. You will also be asked to answer some questions about your alcohol use, drug use, sleep, and motivation to try different activities. These questions are being included as part of our basic health history survey because these

factors have been related to heart rate and physical activity markers being measured in this study.

Why is this study important or useful?
This information will be used to develop programs that will help people lose weight and become healthier with physical activity.

Why have I been asked to be in this study?
You have been asked to be in this study because you are eligible and have expressed interest in participating. You have also met the criteria to be included in this study. Based on the answers that you provided as part of the online screening process, you are a female student at the University of Alabama between 18 and 24 years of age. You have said that you do not currently have an exercise program, and our research team has determined that it is safe for you to exercise.

How many people will be in this study?
About 30 other people will be in this study.

What will I be asked to do in this study?
If you choose to participate in this study, some of the information will be collected from you. This includes information about your health status (heart rate), as well as information about what your body is made of (fat, muscle, and bone), and physical activity (steps, minutes, and sitting time). During the exercise sessions, you will be asked to walk continuously on a treadmill in the Exercise Physiology Lab in Moore Hall. The treadmill will be set to a moderate walking speed, fast enough to increase your heart rate up to 75% of your maximum heart rate, but slow enough so that you can easily walk for 45-60 minutes. You will be asked to visit the lab on 5 consecutive days at the same time each day during the one-week study for your supervised exercise sessions.

If you agree to participate, you will be asked to:
Visit 1 (V1) [Before Week 1] (~90 minutes)
Exercise Physiology Laboratory, Department of Kinesiology
When visiting the lab for V1, you will do the following:

1. Your on-line screening form will be checked for accuracy.
2. The study team will have you read an informed consent document (ICD), and then describe what you will be asked to do for this study. You will also read a consent document for the dual energy x-ray absorptiometry (DXA) body scan. After the study team feels that you understand what you will be asked to do for this study, both you and the study team member will sign the informed consent document and each will keep a copy.
3. Height, weight, and waist measurements will be performed, a lot like the measurements performed in a doctor's office.
4. Your heart rate will be measured each morning by placing three electrodes on your skin just below your collar bone and above your hips. The electrodes will be connected to a desktop computer. You will be asked to lay quietly on an athletic training table for 10 minutes while

the researchers record your heart rate. Next, you will be asked to sit quietly in a chair for 10 minutes, following by standing quietly for 10 minutes while the researchers record your heart rate.

5. You will then have a DXA whole body scan to see what you are made of (fat, muscle, and bone). During the scan, you will be asked to lay on the scanning bed for 7-24 minutes.
6. You will be asked to complete a fitness test to measure your fitness level. During the test, the study team will ask you to walk on a treadmill while breathing through a special mouthpiece to measure the air you breath in and out. The speed and incline of the treadmill will gradually increase until you fatigue and requests to stop. (~20 minutes duration).
7. You will complete a Demographic and Health History Questionnaire so the research team will be able to provide basic descriptive characteristics of the participants in the study. In addition, you will be asked to complete the "Self-Motivation Inventory" to assess your motivation to try new things, the "Pittsburgh Sleep Quality Index" to measure your sleep patterns, and the "GRIT" scale to measure your determination to complete day-to-day tasks. These questionnaires will be completed on a desktop computer in the exercise physiology laboratory (~20 minutes).
8. The activity monitor will be given to you. Everyone in this study will be asked to wear and track her activity during the study. These can measure how much you move around during the day, and also measure your sleep patterns.

Visit 2-5 (V2-V5) [Before Week 1] (~45 minutes)
Exercise Physiology Laboratory, Department of Kinesiology
When visiting the lab for V2-V5, participants will do the following:

1. Your heart rate will be measured each morning by placing three electrodes on your skin just below your collar bone and above your hips. The electrodes will be connected to a desktop computer.
2. You will be asked to lay quietly on an athletic training table for 10 minutes while the researchers record your heart rate. Next, you will be asked to sit quietly in a chair for 10 minutes, following by standing quietly for 10 minutes while the researchers record your heart rate.

Visit 6-10 (V6-V10) [During Week 1] (~90 minutes)
Exercise Physiology Laboratory, Department of Kinesiology
When visiting the lab for V6-V10, participants will do the following:

1. Prior to each exercise training session, 45 minutes will be spent measuring HRV similar to V2-V5, body weight, completing the Profile of Mood States survey, and preparing participants for exercise.
2. During each session, you will be asked to walk continuously on a treadmill at a moderate intensity, equal to 75% of maximum heart rate. A low-intensity warm-up and cool-down period will occur at the beginning and end of each session to ensure that your heart rate returns to normal levels.

Visit 11-15 (V11-V15) [After Week 1] (~45 minutes)
Exercise Physiology Laboratory, Department of Kinesiology

When visiting the lab for V11-V15, participants will do the following:

1. Your heart rate will be measured each morning by placing three electrodes on your skin just below your collar bone and above your hips. The electrodes will be connected to a desktop computer.
2. You will be asked to lay quietly on an athletic training table for 10 minutes while the researchers record your heart rate. Next, you will be asked to sit quietly in a chair for 10 minutes, following by standing quietly for 10 minutes while the researchers record your heart rate.

No contact between you and the study team personnel about missing information will take place after the study. If you choose to participate in the current study no further testing will be asked of you, outside of what is described in the consent document. You do not have to do anything else.

How much time will I spend being this study?
With 15 testing visits, around 16 hours (945 minutes) will be spent in the research lab for data collection.

Will being in this study cost me anything?
The only cost to you from this study is your time.

Will I be paid for being in this study?
You will be paid for being in this study. All participants will receive a total of $10 for completing all testing visits. If you are unable to complete the study or choose to withdraw from participation prior to completing the study, you will be compensated with a prorated amount of $5 for your participation. Because one of the important variables in this study is %Fat, a baseline DXA scan is required for participation in the study. As a result, if you are pregnant or become pregnant during the study you will be withdrawn from the study.

Can the study team take me out of this study?
Yes, the study team can you remove you from the study if you do not follow directions or choose not to comply. You may also be removed if the study team determines it is unsafe for you to continue in the study.

What are the risks (dangers or harms) to me if I am in this study?
The results of the research study may be published, but your name or any information that could identify you will not be used. In fact, the published results will be given in summary form only. Your name, and all other personal information will be removed and replaced with a coded identification number. A potential risk of participating in this study is breach of confidentiality or loss of data-security. However, if you choose to participate in this research study, the research team will limit the potential risks by making sure that all research staff members working with participant data are trained in human subjects research and sensitivity. We also will take steps to keep your identifiable data confidential. **During exercise, it is also possible that you may experience mild muscle soreness.**

There may be some additional risks associated with this study. These may include:

1. Psychological stress from having your weight assessed, answering questions about body image and self-esteem, sexual history, alcohol use, and illicit drug use. However, you have the right to skip without penalty any questions you feel uncomfortable answering.
2. Breach of confidentiality or loss of data-security.
3. Small radiation dose associated with the DXA scan.
4. The occurrence of exercise-related events including the development of abnormal heart beats or death, as well as the less serious problems of injury to tendons, ligaments, joints and muscles.

We will reduce risks to you by doing the following:

1. We will provide you, after you have completed surveys with appropriate information about counseling and psychiatric services on the UA campus.
2. All members of the study team working with you are trained in human subjects research and sensitivity. We also will take steps to keep individually identifiable data private. We understand asking underage college students about alcohol consumption and illicit drug behaviors may cause some stress. But, it is important to collect this data because they are common among college behaviors. This data will help provide accurate descriptions of health statuses and behaviors of college students.
3. DXA scans used to determine body composition involve exposure to radiation from x-rays. The radiation exposure from this procedure is typically 1-5 mrem. A similar amount of radiation is received during a normal day because of natural background radiation exposure to adults in the United States each year. The risk from this amount of radiation exposure is too small to be measured directly and is considered to be low when compared with other everyday risks. Some experts believe there is a theoretical risk that low radiation doses from DXA scanning could harm a fetus but the available evidence shows no harms resulting from accidental scans of pregnant women. Because of the theoretical risk to the fetus, during the screening phase, no females will be enrolled in the study if they indicate they are currently pregnant, trying to become pregnant, or produce a positive pregnancy test during the consent process. A free pregnancy test will be offered to all females prior to the DXA testing. Confidentiality of the pregnancy test results will be followed. There is a risk of discomfort upon learning the results of a pregnancy test and the accuracy of the urine tests we will use are not 100%. Because the DXA scan is a required part of this study, individuals that choose not to take the pregnancy test will only be allowed to participate in the study if they indicate they are not currently pregnant, or not trying to become pregnant during the study. Again, current evidence suggest no harm resulting from accidental scans of pregnant women, however the participant will assume all responsibility from an accidental scan if pregnant.
4. The study team to reduce the possible risk will carefully supervise all testing. In the unlikely event of an emergency, laboratory personnel trained in CPR/AED will be present during all test conditions. In the event of a medical emergency, emergency medical services will be notified immediately. Emergency protocols for handling a cardiovascular problem will be posted in the laboratory during testing.

What are the benefits (good things) that may happen if I am in this study?
After the study, you will be provided with information about your body (fat, muscle, and bone). You will also receive information about your physical activity level. You will be provided supervised exercise training sessions aimed at weight loss under the supervision of exercise and fitness professionals. The exercise prescription will be tailored to you based on your fitness level.

What are the benefits to science or society?
The information gathered through this research study may help in future programs design more effective interventions to prevent overweight or obesity. The results of this study may increase the public health understanding of the health statuses and behaviors of college students and may be used in the future to design health behavior interventions and programs targeted to college students.

How will my privacy be protected?
No additional testing beyond what is described in this consent document will be asked of you after taking part in this study. Also, to protect your privacy, you do not have to answer any questions they do not want to as part of the study requirements.

How will my confidentiality be protected?
Your confidentiality as a student and as a participant in this research study will be protected by a number of methods. First, signed informed consent documents will be kept in a separate location, away from any personal information or research data. In addition, a coded study ID number will be assigned to your name and used with all research data to protect your personal information. Only the principal investigator and study team will have access to personal information before de-identification. The raw data and personal identifiers will be destroyed after the study has been completed. Finally, all hard copies of study information will be kept in a locked drawer and locked in a secure office when unattended. All electronic copies of research data will be kept in a password-protected file.

What are the alternatives to being in this study? Do I have other choices?
The alternative to being in this study is not to participate.

What are my rights as a participant in this study?
If you start the study, you can stop at any time. There will be no effect on your relations with the University of Alabama.

The University of Alabama Institutional Review Board ("the 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.

Is participating in this study voluntary?
Your involvement in this study is voluntary. You can choose not to participate, withdraw your consent, or stop at any time without penalty or loss of benefits to which you are otherwise entitled.

What happens if I am injured while participating in this study?
The study team will exercise all reasonable care to protect you from harm as a result of your participation. In the event that any research-related activities result in an injury, the sole responsibility of the study team will be to arrange for your transportation to an appropriate health care facility. If you think that you have suffered a research-related injury, you should seek immediate medical attention and then contact Dr. Michael Fedewa right away at 205-348-9779. In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

Who do I call if I have questions or problems?
If you have questions about the study right now, please ask them. If you have questions about the study later on, please call the investigator, Dr. Michael Fedewa at 205-348-9779.

If you have questions, concerns, or complaints about your rights as a person in a research study, 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://osp.ua.edu/site/PRCO_Welcome.html or email the Research Compliance office at participantoutreach@bama.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 study team for a copy of it and mail it to the University 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 agree to take part in it.

I will receive a copy of this consent form to keep.

_____ _____
Signature of Research Participant Date

_____ _____
Signature of Investigator Date

UNIVERSITY OF ALABAMA IRB
CONSENT FORM APPROVED: 8-10-17
EXPIRATION DATE: 6-7-18