

Protocol: [REDACTED]
[REDACTED]

INFORMED CONSENT AUTHORIZATION TO PARTICIPATE IN A RESEARCH PROJECT

TITLE: [REDACTED]

PRINCIPAL INVESTIGATORS: [REDACTED] [REDACTED] [REDACTED]

SUBJECT NAME (Please print): _____

This is an invitation to participate in research. This form explains your rights as a research participant. Please take your time to make your decision. Feel free to discuss it with your doctors, family, or anyone you wish. The 'research team' may include physicians and/or other licensed practitioners.

The researchers must give you a copy of this form to keep.

I. STUDY PURPOSE

The purpose of this research study is to find out if one's heart health is affected by life stress, physical inactivity, and by the amount of support received from family and friends. We are interested in finding out if individuals who have these kinds of experiences are at a higher risk to have heart disease.

II. STUDY PROCEDURES

You will be asked to take part in an interview. The interview is about your experiences in various life situations, such as at work, and at home. In addition, we are going to ask about some personal information about yourself, your lifestyle, your activity level, your support from families and friends, as well as questions regarding symptoms of depression. This interview will take approximately 1 1/2 hours. We are going to measure your height, weight, percentage of body fat, and width of your hips and waist, as well as your blood pressure. We are going to do an EKG while you're lying down for 5 minutes. You are going to have a brief physical exam and evaluation by a doctor. You will go home with a small device called an "accelerometer" which will clip on a belt provided to you and that you wear during waking hours for 4-days. We are also asking for you to have a blood draw for laboratory tests and a have a complex x-ray called a CAT scan. The CAT scan will be of your heart, abdomen, and thigh. If you qualify, you will also complete a exercise test during a separate visit.

The EKG will look at the rhythm of your heart and provide information about your heart. Twelve "stickers" will be placed over your chest, legs, and arms. You will lie quietly for 5 minutes on a table.

A doctor will do a brief physical exam to check your heart, lungs, and arteries. You will be dressed. The physician will also ask you questions about various symptoms related

to your medical history and symptoms you may be experiencing. This information will also determine if you are eligible for the exercise test described below.

The laboratory tests will check for cholesterol, kidney function, and other heart blood tests in your body. Only 25 milliliters of blood (about 9 test tubes, not filled completely) will be collected. If you agree, an extra sample of your blood (3 milliliters, less than a teaspoon) will be stored for future tests on heart disease and diabetes. We will not collect this one extra tube if you do not give us your permission. After this, you will drink a high-sugar drink unless you have diabetes or if you are taking medication for diabetes. Small blood samples (about 1 milliliter each, about ¼ teaspoon each) will be drawn 1 and 2 hours later to determine how well your body handles sugar.

If you are a female participant, you will have a urine pregnancy test done. If you have a positive urine pregnancy test, you will not complete the study, and you will be referred to your doctor. If you do not have a doctor, we will give you information about the county hospital or a clinic where you can receive medical care.

You will go home with a small device called an “Accelerometer” which you will wear during waking hours for 4 consecutive days. This device measures your normal daily activity and will not beep nor will you be required to do anything with it other than wear it.

The CAT scan of the heart will be completed at Radiology Associates, Center for Diagnostic Imaging, 3400 Camp Bowie Blvd. Suite 100, lot G. You will lie on a table and a scanner will pass over you. The scanner will be open at both ends and you will not have dye injected into your veins. This will take around 45 minutes to complete.

The CAT scan and the lab tests will be provided to you at no cost.

If you are eligible, the exercise test will be completed in the Physiology Department located in the EAD building, Suite 660, 3500 Camp Bowie Blvd. You will be asked to walk on a treadmill at various difficulty levels to check your fitness level. You may stop the test at any time. This will take approximately 1 hour.

You will receive up to a total of \$100 of gift cards/certificates as a reimbursement for your time and effort for participating in this study. Also, if you need it, we can provide you with bus passes so you can make it to your appointments.

You will also be contacted by phone once a year for 3 years for follow up. We will ask you several questions by phone and the follow up call will last about 20 minutes. You will not be paid for these telephone interviews.

The following is a schedule of the events that will take place:

Visit 1: Interview and Labs

- Because we are performing a CAT scan that uses radiation, if you are a woman, we will do a urine pregnancy test. If the test is positive, you will not be able to participate in the study. You will be referred to your doctor, or if you do not have one, to another clinic.
- You will answer a survey that will take about 1 ½ hours to complete. The Research Assistant (RA) will read the first part, and you will read and answer the 2nd part of the survey. If you prefer, the RA can read all of the questions to you.
- The RA will then measure your weight, height, waist, and hips with a tape measure. The RA will also measure your blood pressure.
- Body fat percentage will be measured by putting “stickers” on your wrists and ankles. You will lie quietly on your back on a table for about 5 minutes while the measurement is made.
- An EKG will be performed which will look at the rhythm of your heart and provide information about your heart. Twelve “stickers” will be placed over your chest, legs, and arms and wires will be connected to these stickers. You will lie quietly on your back on a table for 5 minutes.
- A doctor will do a brief physical exam to check your heart, lungs, and arteries. You will be dressed. The physician will also ask you questions about various symptoms related to these your medical history and symptoms you may be experiencing.
- The RA will schedule your appointment for the CAT scan at Radiology Associates, Center for Diagnostic Imaging, located across the street (3400 Camp Bowie, Suite 100, lot G) at your convenience within 2 weeks. The RA will also schedule you for the exercise test if you are eligible located in the EAD building, Suite 660, 3500 Camp Bowie Blvd.
- You will receive instructions on how to use and wear the Accelerometer, which is an instrument that records your level of activity during the day. You will have a chance to ask any questions about how to use the accelerometer and will be given written information to take home with you explaining the procedures.
- The RA will give you a form to go downstairs to the lab on the 1st floor. They will draw about 5 teaspoons (about 9 tubes) of blood to check for cholesterol, kidney function and other heart-related blood tests. If you agree, an extra tube of blood (less than a teaspoon) will also be collected and stored for future tests on heart disease and diabetes.
- After blood is drawn you will drink a special high-sugar drink which does not contain lactose. 1 milliliter of blood (about ¼ teaspoon) will be drawn 60 minutes after you finish the drink and again 120 minutes after you finish the drink. This test will measure how efficiently your body handles sugar. You will not complete this test if you have diabetes or if you are taking medication for diabetes.
- If we find any abnormal lab results, you will be referred to your doctor. If you do not have a doctor, you will be referred to the county hospital or a community clinic.
- You will receive a \$60 gift card/certificate as a compensation for your time.
- The total time for this visit will range from 3-4 hours.

In Between Visit 1 and Visit 2:

- You will be asked to wear the accelerometer for 4 days including 1 weekend day, from the time you get up in the morning until you go to sleep at night.
- The 4 days can be either Wednesday through Saturday, or Sunday through Wednesday.
- The accelerometer is worn on a belt in a small pouch at the waist. It should be worn for all activities, unless you will be getting wet (such as for showering or swimming).
- You should do your normal activities during these 4 days. You do not have to do any additional exercise.

Visit 2: CAT scan

- You will go directly to Radiology Associates, Center for Diagnostic Imaging, for your CAT scan appointment. Radiology Associates is located at 3400 Camp Bowie Blvd. The radiology team will then give you instructions to follow. The area they will be scanning includes your heart, abdomen, and thigh.
- The total time you will be in the CAT scanner is about 20 minutes.
- If any abnormal results are found, you will be referred to your doctor.
- You will receive a \$20 gift card/certificate as a compensation for your time.
- Copies of all the results will be sent by mail to you and your doctor. If you don't have a doctor, we will give you information about the County hospital or a community clinic.
- The total time for this visit will take about 60 minutes.

Visit 3: Exercise Test

- You will go to EAD 660 for the exercise test. You will need to wear clothing that you can comfortably walk on a treadmill in. You will also need to wear comfortable shoes, preferably shoes made for running or walking.
- Research associates will give you instructions for the test. Electrodes will be put on your chest to monitor your heart, and a blood pressure monitor will be placed on your arm.
- You will start walking on the treadmill at a slow speed and a level grade. The workload will increase every three minutes until you reach a pre-determined heart rate. This pre-determined heart rate is based on your age and your heart rate while you are at rest.
- During the test your blood pressure, heart rate, and heart electrical activity will be closely monitored.
- Once you reach the pre-determined heart rate, the speed and grade will be reduced and you will "cool down" for several minutes. You will have access to towels and water after the test.
- If any abnormal reactions occur during the test, the test will be stopped immediately.
- You will receive a \$20 gift card/certificate as a compensation for your time.
- Total time for this visit is approximately 1 hour.

Post - Follow up

- You will be contacted once a year for 3 years. The follow-up telephone interview will ask you questions about your health and any medical issues that have occurred during the previous year.
- Each interview will take about 20 minutes to complete.
- If we cannot contact you, a research team member will contact your doctor to get this information, or will get the information from your medical records.
- You will not be paid for these follow up telephone calls.

III. RISKS AND DISCOMFORTS OF THE STUDY

The risks associated with this study are minimal.

1. Questionnaire

- a. You may experience some discomfort when answering some of the questions in the survey. If this happens, you may refuse to answer any questions that you find uncomfortable and you may refuse to be seen by a physician.
- b. There is the possibility that the results of your interview and tests may accidentally be revealed to someone other than the study investigators. However, the study investigators will take all precautions necessary to protect your confidentiality as a research study participant. None of your personal identifying information, such as name or address, will be recorded in the study data. Results from this study will not report any of your personal information.

2. EKG

- a. You may experience discomfort and/ or breathing difficulty from lying on your back.
- b. You may have skin irritation at the sites of the adhesive electrodes or "stickers".

3. Physical exam

- a. There may be some discomfort, such as embarrassment, when having the physical exam. You will be dressed during the exam.

4. Accelerometer

- a. There may be a small amount of discomfort due to having to wear an extra belt all day. Belts can be worn over or under clothing.

5. Laboratory testing

- a. You may experience some minor pain from the blood draw where the needle was inserted, blood clot, or in rare cases, a bruise or infection.
- b. Standard blood draw precautions will be taken to minimize any of these risks.
- c. If you agree, the extra blood sample (about a teaspoon) will be stored for future studies on heart disease and diabetes. Your stored blood sample will not include your name or anything else that could identify you. The only information linked to the blood sample will be your race/ethnicity, age, gender, body measurements, electrocardiogram (EKG) results, your survey responses, blood and CAT scan

results, and your activity/exercise test results. Only the research investigators will have access to these blood samples.

6. CAT scan

- a. You may experience discomfort and/ or breathing difficulty from lying on your back.
- b. Radiation levels of the CAT scans are about equal to the amount radiation someone is normally exposed to being outdoors for 24 months. This level of radiation is common for many patients who receive a CAT scan that is ordered from their doctor. For example, one regular abdominal CAT scan ordered by a doctor is equal to being naturally exposed to radiation from being outdoors for 36 months (or 3 years).
- c. Pregnant women participants will not complete the CAT scan because there is a risk of damage to the fetus.

7. Exercise test

- a. There is a certain risk associated with any exercise test. The risks may include abnormal increase or decrease of blood pressure, irregular heartbeats, light-headedness, psychological discomfort, physical injury, and, in rare instances, heart attack or death.
- b. A death rate that occurs in maximal exercise stress test is about 1 out of 10,000 chance. However, you will NOT be doing a maximal exercise test so the risk is even lower.
- c. The exercise test will be stopped whenever you want to stop; also, we will stop the exercise test if your blood pressure is too high or if there is any problem in your heart rate which is considered alarming, such as a significant number of extra beats or unusual heart beats are observed.

IV. CONTACTS

If a study-related problem should occur, or if you have any questions at any time about the study, you may contact [REDACTED], Research Coordinator, at (817) 735-[REDACTED]. If you have any questions about your rights as a participant in this study, you may contact Dr. Brian Gladue, Chairman of the Institutional Review Board, University of North Texas Health Science Center at Fort Worth at (817) 735-0409.

If you are a JPS Health Network Patient and have any questions regarding your rights as a subject participating in this study, you may contact Debbie Wilkinson-Faulk, Ph.D. or another member of the JPS IRB at (817) 927-1173.

V. BENEFITS

You may receive no direct benefit from participating in this study. The information gained from this research may lead to the development of better ways to prevent heart disease that might be related to discrimination, life stress, physical activity, and lack of support from family and friends.

VI. ALTERNATIVES

This study involves one interview, physical exam, EKG, accelerometer, blood draw, CAT scan, exercise test, and up to three phone calls for follow-up purposes. There are no additional treatments or interventions involved in our study, other than what has been explained. Therefore, the only alternative to our study is to not participate in the study.

VII. CONFIDENTIALITY

Your interview responses will be kept as confidential as possible under current local, state, and federal laws. However, the Office for Human Research Protections, possibly other federal regulatory agencies, and the Institutional Review Board may examine your interview responses and the study data. In the case the final results of this study should be published, no individual results will be reported, and your name will not appear in any published material.

VIII. COMPENSATION FOR INJURY

We at the University of North Texas Health Science Center at Fort Worth, and JPS Health Network have not set aside any funds for financial compensation for costs of medical treatment should you be injured as a result of your participation in this research.

You should know that by signing this form you are neither waiving any of your legal rights against nor releasing the investigators conducting this study, nor the University of North Texas Health Sciences Center at Fort Worth or any of their respective agents from liability for negligence with respect to the conduct of this study. If you are harmed and you feel that this harm justifies pursuing a legal remedy, you have the right to do so.

If you are injured or have an adverse reaction because of this research, you should immediately contact one of the personnel listed in section IV. Contacts. Emergency medical treatment will be available at JPS Health Network hospitals at no cost to you. No additional compensation will be provided. Agreeing to this does not mean that you are giving up any legal rights that you may have

IX. COSTS AND PAYMENTS OF THE STUDY

You may receive up to a total of \$100 worth of gift cards/certificates as a compensation for your time and effort for participating in the study. That is, you will receive \$60 for participating in visit 1 and the take home activity (wearing the accelerometer) between visits 1 and 2, \$20 for participating in visit 2 and, and \$20 for participating in visit 3. Even if you are not able to complete the visit for any reason, you will receive the gift card/certificate for the entire amount for that specific visit. Laboratory tests, CAT scans, and the exercise test will be provided to you at no cost. We will also provide you with bus passes if you need them.

X. LEAVING THE STUDY

You can choose not to be in the study or leave it (discontinue the interviews, blood draw, EKG, exercise test, or CAT scan) at any time without penalty or loss of benefits that you are otherwise entitled. Your participation (or non-participation), or any response that you give, will in no way affect the care that you receive at your clinic.

If you are a student or employee of the University of North Texas Health Science Center at Fort Worth, your participation (or non-participation) will in no way affect your academic standing or employment status.

XI. CONSENT

I voluntarily agree to participate in this study. I have had the chance to ask the study investigators any questions I have regarding this study.

YOU WILL RECEIVE A COPY OF THIS SIGNED INFORMED CONSENT AGREEMENT.

Signature of Study Participant

Date

Signature of Person Obtaining Informed Consent

Date

I consent to providing an extra sample of my blood to be stored for future studies related to heart disease and diabetes as explained to me in this document.

Signature of Study Participant

Date

Protocol Title: [REDACTED]

Principal Investigators: [REDACTED] D.O., M.P.H., [REDACTED], Ph.D.

**ADDENDUM TO INFORM CONSENT FORM FOR PARTICIPATING IN A HUMAN RESEARCH STUDY
(HIPAA AUTHORIZATION FOR USE OF PROTECTED HEALTH INFORMATION IN RESEARCH)**

The word “you” means both the person who takes part in the research, and the person who gives permission to be in the research. This form and the attached research consent form need to be kept together.

Purpose of this form:

You have been asked to take part in a research study. The consent form for this study describes your participation, and that information still applies. This addendum is required by the federal “Health Insurance Portability and Accountability Act” (HIPAA). The purpose is to get your permission (authorization) to use health information about you that is created by or used in connection with the research. If you are signing on behalf of someone other than yourself, this permission applies to that person’s health records.

Authorization to Use Health Information:

The investigators named above and their assistants will be allowed to see and to use your health information for this research study. We may share your health information with people at the hospital, JPS Health Network, or the UNT Health Science Center who help with the research. We may share your information with other researchers outside of the Health Science Center, JPS Health Network or with labs running additional tests. We may also share your information with people outside of the Health Science Center, or JPS Health Network who are in charge of the research, pay for or work with us on the research, or by the U.S. Food and Drug Administration (FDA), in order to check for quality, safety or effectiveness. Some of these people make sure we do the research properly. The “confidentiality” section of the consent form says who these people are. Some of these people may share your health information with someone else. If they do, the same laws that the Health Science Center or JPS Health Network must obey may not protect your health information.

We are asking you to take part in the research described in the attached consent form. To do this research, we need to collect health information that identifies you. The information we might use or disclose includes:

- Supporting information from your medical record, including laboratory and vital signs (blood pressure, weight, and height).
- Your responses to the study interview questions.
- Body measurements (height, weight, and waist/hip width)
- Results of the blood laboratory testing, EKG, physical exam, accelerometer, exercise test, and CAT scan

In order for you to participate in this study, we need your permission to collect and share this information.

Term of Authorization:

If you sign this form, we will collect your health information until the end of the research. We may collect some information from your medical records even after your direct participation in the research project ends.

We will keep all the information as long as necessary, in case we need to look at it again. We will protect the information and keep it confidential.

Refusal to sign/Right to Revoke:

If you sign this form, you are giving us permission to collect, use and share your health information. You do not need to sign this form. If you decide not to sign this form, you cannot be in the research study. You need to sign this form and the attached consent form if you want to be in the research study. We cannot do the research if we cannot collect, use and share your health information.

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to the researcher listed on the attached consent form. The letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. However, we may still use the information we have already collected, since we need to know what happens to everyone who starts a research study, not just those people who stay in it.

Questions regarding your privacy rights:

Any questions? Please ask the researcher coordinator, [REDACTED], at 817-735-[REDACTED]. You can also call 817-735-[REDACTED] with questions about the research use of your health information. The researcher will give you a signed copy of this form.

SIGNATURE, DATE, AND IDENTITY OF PERSON SIGNING

By signing this form, I am giving permission for the personal health information about _____ to be collected and used as described above by the researchers and staff for the research study described in this form and the attached consent form. I will be given a copy of this authorization form after I have signed it.

Signature: _____ Date: _____
Print name: _____ Relation: _____