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COMPENSATION LANGUAGE

Compensation above \$100

Per University Policy, to pay you we will need to collect your social security number or Individual Taxpayer Identification Number for tax purposes. If you do not want to provide this information, you can still be in the research study, but we cannot pay you.

CONFIDENTIALITY LANGUAGE

Audio, Video, Image Release

The results of this study may be published or presented at a scientific meeting. The researchers will ask for separate written permission to include your [name, pictures, and/or recordings] or other information that could identify you.

Certificate of Confidentiality

We have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS) for this study. This certificate adds special protection for research information that identifies you. This Certificate does not mean that the government approves or disapproves of this study.

With this Certificate, we cannot be forced (for example by court order or subpoena) to release any identifying research information about you. You should understand that the Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your participation in this research study. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate does not prevent the researchers from voluntarily disclosing, without your consent, information that would identify you as a subject in this research study if we: 1) are concerned that you may be suicidal or at immediate risk of seriously harming yourself or others, or 2) learn about serious harm to you or someone else (such as child abuse or elder abuse). Under these circumstances we will notify the appropriate people (such as your personal doctor, counselor, local or state agency, or other authorities).

Internet-based research

Confidentiality will be maintained to the degree permitted by the technology used. Your participation in this online survey involves risks similar to a person's everyday use of the Internet, which could include illegal interception of the data by another party. If you are concerned about your data security, please contact the researcher to schedule a time to complete a printed survey with the same questions.

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CONFLICT OF INTEREST LANGUAGE

[Name of individual with COI] is a named inventor on patents or patent applications or is the creator of copyrighted material that is licensed or optioned to [company name] that will be used in this research. This means [individual with COI] could gain financially from this study.

[Insert name of individual with COI] has a financial interest in the company sponsoring this study. [Briefly describe the financial interest.]

[Name of individual with COI] has received personal compensation from the sponsor of this study in the past for his/her work on [project/technology/item/board] and may receive personal compensation from the sponsor in the future.

DEFINITIONAL LANGUAGE

DNA

Your genes are made up of DNA. DNA is short for deoxyribonucleic acid. A gene, or DNA, contains information that determines in part the traits such as eye color, height, or disease risk, that are passed on from parent to child.

RISK LANGUAGE: BIOMEDICAL

Allergic Reaction Risks

Occasionally, people may have allergic reactions to [enter drug/supplement name] that may require medical treatment. A severe allergic reaction could be life threatening. Examples of an allergic reaction can include: a rash, shortness of breath, wheezing, difficulty breathing, sudden drop in blood pressure, swelling around the mouth, throat, or eye, fast pulse, and sweating. If any of these reactions occur, you should get immediate help. When you are able, contact the study doctor if you have any of these or any other side effects during your participation in the study.

Blood Draw Risks

Blood samples will be taken from a vein in your arm during the study. The taking of a blood sample may cause some discomfort and bruising, and there is a potential for infection. Other risks, although rare, include dizziness and fainting.

Blood Pressure & Heart Rate

An inflatable cuff will be placed on your arm and a machine will measure your blood pressure and heart rate, after you have been sitting down for 10 minutes. You may experience mild discomfort in your arm when the cuff is inflated.

Echocardiogram

A gel will be spread on your chest, and then the transducer will be applied. You will feel a slight pressure on your chest from the transducer. You may be asked to breathe in a certain way or to roll over onto your left side. This test is not painful.

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Electrocardiogram (ECG)

This is a painless test that shows how your heart works (takes a picture of the electrical activity of your heart). To have the ECG, you will lie on a bed/couch for several minutes and small sticky pads will be put on your chest, shoulders and hips. The machine will measure the electrical activity of your heart. We may need to clip small patches of your hair in these areas. These sticky pads may cause skin irritation and it may cause some discomfort when they are removed.

Electroencephalogram (EEG)

An electroencephalogram (EEG) measures the electrical activity in the brain (brain waves) using electrodes (small metal discs or sensors) placed on the head with gel. The test does not hurt and usually takes about an hour. The gel used to put the discs on your head is sometimes sticky and the discs may scratch a little bit.

MRI Risks

There are no known harmful effects from the strong magnetic field used for MRI. But the magnet is very powerful. The magnet may affect pacemakers, artificial limbs, and other medical devices that contain iron. The magnet will stop a watch that is close to the magnet. Any loose metal object has the risk of causing damage or injury if it gets pulled toward the strong magnet. Before you have the MRI, we will ask you about any metal within your body (this includes certain dyes in tattoos). You will need to remove all metal objects (such as hearing aids, dentures, jewelry, watches, and hairpins) from your body because these objects may be attracted to the powerful magnet used for the test.

You should not have an MRI if you have claustrophobia (fear of small spaces). The top and sides of the machine will be very close to your body. Because of this, you may feel anxious while inside the MRI machine. If you do feel anxious during the procedure, you can ask us to stop the MRI at any time.

[Use if applicable to study population] If you are pregnant or suspect you are pregnant, you should inform the study staff before the MRI examination. Although there is no known risk of using MRI in pregnant women, the safety of MRI during pregnancy has not been established. Therefore, you cannot have an MRI for this study if you are pregnant or think that you are pregnant.

Pregnancy/Breastfeeding Risks

Taking part in this study while you are pregnant could cause harm to your fetus. If you are breastfeeding, taking part in this study could cause harm to your baby. You must not take part in this study if you are pregnant or breastfeeding. If you are a sexually active woman of childbearing age and would like to take part in this study, talk with the researcher about ways to avoid pregnancy. If you think that you have become pregnant while taking part in this study, you must contact the researcher right away.

Radiation Risks

Procedures such as DXA scans, CT scans, and/or X-rays will be used during this research study. The cumulative radiation exposure from these tests is considered small and is not likely to

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adversely affect you **or your disease**. However, the effects of radiation add up over a lifetime. It is possible that having several of these tests may add to your risk of injury or disease. When deciding to enter this study, think about your past and future contact with radiation. Examples of contact with radiation include x-rays taken for any reason or radiation therapy for cancer treatment.

RISK LANGUAGE: SOCIAL, BEHAVIORAL, OR EDUCATIONAL RISKS

Deception/Incomplete Disclosure

As part of this research, you will not be told about some of the study details. If you were told these details at the beginning of the study, it could change the research results. If you decide to be part of the study, you will be provided an explanation of what information was withheld from you at the end of your study participation.

Focus Groups

The researchers will ask you and the other people in the group to use only **first names/pseudonyms** during the group session. They will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private.

Interviews

You may feel emotional or upset when answering some of the questions. Tell the interviewer at any time if you want to take a break or stop the interview.

Psychological Testing/Sensitive Topics

This research study involves psychological testing. The questions being asked may be sensitive and personal in nature. It is possible that answering some questions may cause some stress.

Insert options for subject if they should feel uncomfortable providing a response or become distressed, e.g., they can skip any questions, they will be referred for counseling, etc.

Questionnaire/Survey Risks

You may be uncomfortable with some of the questions and topics we will ask about. You do not have to answer any questions that make you feel uncomfortable.