***Changing how the brain responds when making decisions: Translating neuroscience to population health***

IRB: University of Kansas Medical Center Human Subjects Committee
3901 Rainbow Blvd.
Kansas City, Kansas 66160
HSC Assurance #M1122-01

Date of Consent Form: 03/12/19

Protocol #: 142526

Principal Investigator: Laura E. Martin, Ph.D.
Mail Stop 1052
3901 Rainbow Blvd
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**Neuroimaging Studies of Health, Emotions, and Money**
**Protocol # 142526**

**Investigator: Laura Martin, Ph.D.**
**University of Kansas Medical Center**
**913-588-7279**

You are being asked to take part in this study because you are currently overweight or obese. You do not have to participate in this research study. The main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at the University of Kansas Medical Center (KUMC).

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read the form carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating.

This research study will take place at the University of Kansas Medical Center (KUMC) with Dr. Laura Martin as the researcher. About 20 people will be in the study at KUMC.

## BACKGROUND

Neuroimaging studies have identified brain regions that help people make decisions. Different people make different decisions under the same circumstances. The investigators want to build on these findings to see how the brain activity may be different when people make different types of decisions.

## PURPOSE

The purpose of this investigation is to learn about the associations between monetary decisions and psychological, emotional and physical health and well-being.

## PROCEDURES

If you are eligible and decide to participate in this study, your participation will include 2 visits to Hoglund Brain Imaging Center. You may be asked to fast for 2 hours prior to each visit. Your participation will involve one visit to complete questionnaires and an Magnetic Resonance Imaging (MRI) scan and a second visit approximately one week later to complete questionnaires and a computer task. The first visit will last about 2.5 hours and the second visit will last about 1 hour. In addition, you will be asked to track what you eat for approximately 5-days between the two appointments. We will allow a buffer period for sessions to compensate for conflicting schedules (i.e. scanner maintenance, appointment reschedules, subject availability, etc.).

We will re-evaluate your eligibility at each appointment.

Appointment 1: During the first appointment you will complete approximately 1 hour of testing, approximately 1 hour of brain imaging, and approximately 30 minutes of testing following the MRI.

Behavioral Testing: You will be asked to complete several questionnaires assessing wellness and a decision task on the computer before and after going in the scanner.

MRI Testing: You will complete one MRI session. During the MRI testing, you will lay on a table that "slides" into the scanner. Your head will be positioned within the scanning coil. This coil will come close to your face and partly restrict you from moving your head. The MRI evaluation takes about one hour to complete. During the MRI session you will be shown pictures and may be asked to make decisions based on these pictures while you are in the scanner. These pictures may include food and nonfood objects. During the MRI you will also listen to a recording approximately 5 minutes long instructing you to think about physical sensations and/or future events. Your total time in the MRI scanner will be about 1 hour. Part of this MRI testing will involve special investigational MRI software which is used in this research.

Daily Monitoring: You will complete a series of daily consumption surveys that ask you to summarize what you ate each day. You will complete about 5 daily consumption surveys over about 5 consecutive days. You may receive follow up phone calls and text prompts to remind you to record your food and address any questions.

Appointment 2: During the final appointment (about 1-week later) you will again complete several questionnaires assessing wellness and a decision task on the computer.

**RISKS**

During the MRI, you will be by yourself in the scan room, although a technologist or an investigator can stay with you if you wish. It is important that you complete the metal screening form accurately prior to each evaluation. If you have a pacemaker, blood vessel clips, or other internal metal, you may not be allowed to participate in this study. If you have a pacemaker or vascular clip and accidentally enter the MRI suite, a life-threatening situation can develop. If between visits you have any devices surgically implanted, or if you have an accident that results in metal being implanted in your body, the investigators will need to know. If that happens, you may not be able to continue the study. Some subjects get a feeling of mild claustrophobia during MRI. To help lessen this, the MRI unit has a mirror so that you can see outside of the scanner. Also, the MRI unit makes loud noises during the examination. This is normal for an MRI examination but may be somewhat louder due to the investigational nature of some of the MRI software used in this study. To minimize any possible discomfort from these, you will be given earplugs and ear phones to block the noise.

You might be embarrassed by some of the questions the researchers ask you. You are free not to answer any questions.

There may be other risks of the study, including potential risks related to investigational MRI software, that are not yet known.

**NEW FINDINGS STATEMENT**

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

**BENEFITS**

You will not benefit directly from participating in this study. Researchers hope the information from this research study will be useful in providing new insights into how the brain functions and decision-making.

Although your data will be reviewed by our scientific team for the presence of abnormalities, the data from this study are generally NOT reviewed by a physician. Study data are typically

inadequate for clinical diagnoses, and are not intended for this purpose. Since part of the MRI testing involves the use of investigational MRI software, it is not for standard diagnosis and treatment. Also, your research data are not routinely provided to your physicians. If we do identify a possible abnormality, we will pass this information to your doctor (if so requested), and we may recommend follow-up imaging procedures using clinical (rather than research) protocols.

**ALTERNATIVES**

Participation in this study is voluntary. Deciding not to participate will have no effect on the care or services you receive at the University of Kansas Medical Center.

**COSTS**

There is no cost for being in the study.

**PAYMENT TO SUBJECTS**

You will be paid up to $115 for your participation in this study. If you are eligible you will receive the following payments for each appointment you attend:

Appointment #1: $30 for your time
Appointment #2: up to $85 for completing the appointment ($55 for your time & $5 for each day, up to 6 days, all food is recorded)

If you choose to withdraw from the study prior to completing the study you will be paid a prorated amount of money for your time

You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money.

You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

**IN THE EVENT OF INJURY**

If you experience any harm during this study, you should immediately contact Dr. Martin at 913-588-7279. If it is after 5:00 p.m., a holiday or a weekend, you should call the emergency room.

If you have a bodily harm as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party, but you will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

**INSTITUTIONAL DISCLAIMER STATEMENT**

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow for payment to persons who are injured in research at KUMC.

**CONFIDENTIALITY and Privacy Authorization**

The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Your health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities. You may be identified by information such as name, address, phone, date of birth, social security number, or other identifiers. Your health information will be used at KU Medical Center by Dr. Martin, members of the research team, the KUMC Research Institute, the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies. Study records might be reviewed by government officials who oversee research, if a regulatory review takes place.

If you sign this form, you give the study team permission to share your research information with people outside KUMC. These groups or agencies may make copies of study records for audit purposes or to analyze or make sure the study is done properly. These groups may include:

- Groups that help provide or process the MRI data including Siemens Medical Solutions USA and the University of Minnesota (providers of the investigational MRI sequence)
- Experts who inspect the study information to see if the study is being done correctly and if it is still safe to continue
- The FDA or other federal agencies that oversee human research (if a study audit is performed).

Some of the persons or groups who receive the health information may not be required by law to protect it. Once the information is shared outside of KUMC, it might be disclosed by others and no longer protected by the federal privacy laws or this authorization.

The HIPAA privacy law may not apply to everyone who receives your health information. Your information might not be protected by HIPAA if persons outside KUMC disclose it. In some cases, there might be other laws that protect your information from improper use.

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Your permission to use and share your health information remains in effect until the study is complete and the results are analyzed. After that time, researchers will remove personal information from study records.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

**QUESTIONS**

Before you sign this form, Dr. Laura Martin or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

**SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY**

You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC. The entire study may be discontinued for any reason without your consent by the investigator conducting the study.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Martin. The mailing address is Hoglund Brain Imaging Center, University of Kansas Medical Center, 3901 Rainbow Boulevard, Mailstop 1052, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The research team will stop collecting any additional information about you. The research team may use and share information that was gathered before they received your cancellation.

**CONSENT**

Dr. Laura Martin or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
***You will be given a signed copy of the consent form to keep for your records.***

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

## Research Database Addenda (Optional)

In addition to the main study, you are also being asked to participate in an optional separate study involving the creation of a research database. You can participate in the main study without needing to agree to participate in this optional database.

You will not directly benefit from participating in the database.

If you agree to participate in the database, information collected during today's testing, including the images of your brain, will be copied and stored in the research database. This information will be saved indefinitely. It will be used now by Dr. Martin and members of the research team. It may be used in the future by researchers both at KUMC and outside KUMC to help answer questions about memory, thinking, and aging. It will not be used for any other research purposes.

If your information is shared with other researchers, it will be sent using a code number, your date of birth, and the date the information was collected. It will not include your name or identify you in any other way. By limiting the information, we will protect your privacy and lessen the risk of your identity being re-disclosed to outside individuals. If study records are inspected, only authorized persons will have access to your information.

Even if you agree to participate in the database now, you have a right to change your mind later. You may cancel your permission to use your information in the future by sending a request to Dr. Laura Martin, University of Kansas Medical Center, 3901 Rainbow Boulevard, Mail Stop 1052, Kansas City, KS 66160. The research team may use and share information that was gathered before they received your cancellation.

Allowing us to store your information is completely voluntary. If you decide not to sign this consent addendum, then we will not store your information in the research database. If you have any questions about the research, you may call Dr. Martin at (913)588-7279.

Permission to be included in the MRI Database

_____ I agree to allow my data from this study to be stored indefinitely in the KU Structural MRI database for future research use.

_____ I do not agree to allow my data from this study to be stored indefinitely in the KU Structural MRI database for future research use, but it may be used for purposes of this study only.

In the future, researchers at KUMC will be conducting additional studies from data included in the MRI database, which may require additional information. Please check the appropriate line to indicate whether or not you are willing to have us contact you when such future studies come up:

_____ Yes, I am willing to be contacted about future studies for which I might be eligible.

_____ No, I do not want to be contacted about future studies for which I might be eligible.

A separate consent would be obtained at the time of your participation in any additional studies.

I will be given a signed copy of this consent form to keep for my records.

_____
Type/Print Participant's Name

_____ _____ _____
Signature of Subject Time Date

_____
Type/Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date