Cover page for Clinicaltrials.gov

Informed Consent Document

Official title: Short Term Choline Supplementation and Cardiovascular Health in Adults.

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RESEARCH SUBJECT CONSENT FORM

Title: Short Term Choline Supplementation and Cardiovascular Health in Adults.

Protocol No.: 18-535

Sponsor: Virginia Tech

Investigator: Kevin Davy, PhD
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Daytime Phone Number: 540-231-3487

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Human Integrated Physiology Number: 540-231-8299

The purpose of this research study is to determine if short term choline supplementation, which increases the chemical marker trimethylamine N-oxide (or TMAO), affects vascular health in adults. You are being asked to be involved in a study where you will consume a choline supplement for 4 weeks and placebo (sugar pill) for 4 weeks. During the study, you will be asked to avoid specific foods (red meat, fish, eggs) the day before testing and come to the lab after an overnight fast (not consume any food or drink for 12 hours). After baseline testing you will be randomized (a process similar to flipping a coin) to determine the order you consume the choline supplement or placebo (a carbohydrate called maltodextrin) supplement. The choline supplement is made from plant sources and is produced in a laboratory; it is not made from any animal products.

Blood samples (approximately 2 teaspoons total per draw) and a series of tests will be performed at twelve time points. Body weight, heart rate, and blood pressure will be measured every visit. During visits to the laboratory, you may be asked to wear a face mask that is provided to cover your nose and mouth. Research personnel may be wearing masks as well during your visit. You will first come into the laboratory for a screening visit. After screening, you will come to the laboratory for three days for baseline testing followed by four weeks of supplementation. After consuming the choline or placebo supplements for four weeks, the same three days of tests will be performed.

You will then return to your normal diet for 2 weeks. After this, you will come to the laboratory again for three days for baseline testing followed by four weeks of supplementation. After consuming the choline or placebo supplements for four weeks, the same three days of tests will be performed.

There are risks and possible discomforts for the testing procedures performed in this research study. Possible risks and discomforts are described in detail in the consent form below. We cannot promise any benefits to you or others from your taking part in this research. However, as a result of your participation, you will obtain health information related to your body composition, blood pressure, blood glucose, and cholesterol. Your participation will contribute to improving the understanding of how choline intake may impact health.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant. Participation in this study is completely voluntary and you are free to withdraw from the study at any time for any reason. If you chose to participate, the study will consist of 19 visits and require approximately 36 hours of your time.

You will not be able participate in the part of the study that involves taking nitroglycerine if you take Cialis or Viagra.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

Choline is a vitamin-like nutrient needed for many body functions. Intake of choline has been found to produce a chemical marker called trimethylamine N-oxide (or TMAO) that may impact your risk level for cardiovascular disease. Little is known about the effect of TMAO on vascular health. The purpose of this research is to determine if short term choline supplementation, which increases TMAO, affects health in adults. About sixty subjects who are 18-79 years of age will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last 36 hours over 19 visits to the Human Integrated Physiology Lab in Suite 1575 of the Garvin Building at Virginia Tech. The actual

time and frequency of your visits may depend on your and the study staff's schedule.

What happens to me if I agree to take part in this research?

You are being asked to be involved in a study where you will consume a choline supplement and placebo (sugar pill) for 4 weeks and the night before testing sessions. Fourteen capsules will be given to you after baseline testing and you will be asked to consume two capsules once a day in the morning for 7 days. Every week, you will come to the laboratory to receive the next week's capsules. If you agree to be involved in this study, you will first have to fill out a series of questionnaires about your health history, physical activity, infection/inflammation history, and diet (for 4 days). Your results may be discussed with the study medical director to determine if you can be a subject. If you take medications (e.g., antibiotics) or vitamins or supplements (e.g., choline) that influence the study results, you will not be eligible for this study. You may be eligible to participate if you are between 18 and 79 years of age.

During the study, you will be asked to avoid specific foods (red meat, fish, eggs) the day before testing and come to the lab after an overnight fast (not consume any food or drink for 12 hours). During the 10-week study, you may be given food to consume throughout this intervention study or you will be instructed to continue your own diet. The food will similar to that typically consumed in your diet. After baseline testing, you will be randomized (a process similar to flipping a coin) to determine the order you consume the choline supplement or placebo (a carbohydrate called maltodextrin) supplement. The choline supplement is made from plant sources and is produced in a laboratory; it is not made from any animal products. You will have an equal chance of receiving the choline supplement first followed by the placebo or receiving the placebo first followed by the choline supplement.

Blood samples (approximately 2 teaspoons total per draw) and a series of tests will be performed at twelve time points. Body weight, heart rate, and blood pressure, will be measured at every visit. You will first come into the laboratory for a screening visit. After screening, you will come to the laboratory for three days for baseline testing followed by four weeks of choline or placebo supplementation. After consuming the choline or placebo supplements for four weeks, the same three days of tests will be performed. You will then return to your normal diet for 2 weeks. After this, you will come to the laboratory again on three days for baseline testing followed by four weeks of choline or placebo supplementation. After consuming the choline or placebo supplements for four weeks, the same three days of tests will be performed.

There will be 19 visits, if you participate in the study. The entire study will require approximately 36 hours of your time. The actual number and order of visits will depend on your and the study staffs' schedules.

Session 1: (Approximately 2 hours) Garvin Building, Suite 1575
Baseline (Screening) Visit
Overnight Fast: You will be asked to avoid eating or drinking anything except water and to avoid consuming any caffeine-containing beverages for 12 hours prior to this visit so that the test results will not be influenced by the food you eat or by the normal digestion process.

Medical History: You will be asked to complete a medical history questionnaire. This questionnaire is used to screen for health problems or reasons you should not participate in this study. If you have a history of coronary heart disease without current chest pain or heart failure, we will need written permission from your physician for you to participate. Your height and weight will also be measured at this time. Your body weight will be measured on a scale. Your height will be measured with a type of ruler.

Proof of COVID-19 Vaccination: You will be asked to bring proof of COVID-19 vaccination (card or scanned copy) to the laboratory.

Physical Activity Assessment: You will be asked a series of questions to estimate your usual physical activity level. This questionnaire will require about 5 minutes to complete. In addition to the questionnaire, you will be asked to wear a device called an accelerometer, which measures your physical activity level, on 3 weekdays and one weekend day. The accelerometer is about the size of a large watch and attached to a belt to be worn around your waist.

Infection/Inflammation Questionnaire: You will be asked to complete a questionnaire about any recent illnesses or infections that you may have had in the past month.

Diet Records: To get an idea of what and how much food you eat, you will be asked to record all of the food and drinks you have for 4 days (3 weekdays and one weekend day).

Blood Draw: Blood samples will be taken to evaluate different markers (e.g., glucose, cholesterol, and chemical markers that influence cardiovascular health). A needle will be placed in your arm vein to take blood samples (approximately 2 teaspoons).

Blood Pressure, and Heart Rate: You will be asked to rest quietly for 15 minutes. We will then measure your resting blood pressure using a stethoscope and standard blood pressure cuff or an automatic blood pressure monitor. Your heart rate will be determined by the automatic monitor. Your heart rate may also be determined by placing a sensor on your index finger.

Urine Test: You will be asked to urinate in a small cup that we provide you. We will measure the amount of sodium and other electrolytes, glucose, protein, pH and whether there are blood cells present to determine if it is safe for you to participate in the study.

Session 2, 8, 11, 17: (Approximately 3 hours) Garvin Building, Suite 1575
Overnight Fast: You will be asked to avoid eating or drinking anything except water and to avoid consuming any caffeine-containing beverages for 12 hours prior to this visit so that the test

results will not be influenced by the food you eat or by the normal digestion process.

Infection/Inflammation Questionnaire: You will be asked to complete a questionnaire about any recent illnesses or infections.

Blood Pressure and Heart Rate: You will be asked to rest quietly for 15 minutes. We will then measure your resting blood pressure using a stethoscope and standard blood pressure cuff or an automatic blood pressure monitor. Your heart rate will also be determined by the monitor or by placing a sensor on your index finger.

Body Mass: Your body weight will be measured on a digital scale.

Dietary Intake Analysis (24-hour recall): You will be asked to recall all the food and beverages you consumed in the previous 24-hour period.

Oral Glucose Tolerance Test: One small plastic tube (catheter) will be placed in one of your arm veins. After a baseline blood draw to measure glucose, insulin, cholesterol, and other factors, you will drink a sugary drink of glucose (75 grams) and blood will be collected in small amounts (less than one half teaspoon) every half hour (4 blood draws total) over a 2-hour period.

Stool Collection: You will be given a test tube and asked to collect a stool sample. You will be asked to bring the sample back to the laboratory during your next scheduled visit. All supplies and instructions will be provided by study staff.

Continuous Glucose Monitoring: Glucose will be measured by a continuous glucose monitor and this will be placed on your skin on the back of your upper arm. The device will be worn for 3-4 days.

Session 3, 9, 12, 18: (Approximately 2 hours) Garvin Building, Suite 1575
Overnight Fast: You will be asked to avoid eating or drinking anything except water and to avoid consuming any caffeine-containing beverages for 12 hours prior to this visit so that the test results will not be influenced by the food you eat or by the normal digestion process

Infection/Inflammation Questionnaire: You will be asked to complete a questionnaire about any recent illnesses or infections.

Blood Pressure and Heart Rate: You will be asked to rest quietly for 15 minutes. We will then measure your resting blood pressure using a stethoscope and standard blood pressure cuff or an automatic blood pressure monitor. Your heart rate will also be determined by the monitor or by placing a sensor on your index finger.

Body Mass: Your body weight will be measured on a digital scale.

Dietary Intake Analysis (24-hour recall): You will be asked to recall all the food and

beverages you consumed in the previous 24-hour period.

Blood Draw: Blood samples will be taken to evaluate different markers (e.g., glucose, cholesterol, and chemical markers that influence cardiovascular health). A small needle will be placed in your arm vein to take blood samples (approximately 2 teaspoons).

Arterial Stiffness: To measure arterial stiffness, the blood flow and diameter in the arteries in your neck will be measured with an ultrasound machine. An ultrasonic machine is sort of like radar – a low frequency radio wave that bounces off the tissues and sends a picture back to a "TV-like" screen. A mobile hand unit will be pressed gently against an artery in your neck. In addition, we will use a pressure transducer to measure the speed at which your pulse travels in your arteries by placing a fingertip probe on the arteries in your neck, arm, and leg.

Brachial Artery Function: To measure brachial artery function, the blood flow and diameter of your brachial artery in your arm will be measured with an ultrasound machine before and after the inflation of a blood pressure cuff on your forearm for 5 minutes and after placing a nitroglycerine tablet (0.4 mg) under your tongue. You will not be allowed to complete the nitroglycerine aspect if you have a history of coronary heart disease. This procedure takes a total of about 20 minutes to complete and assesses different kinds of brachial artery function.

24-hour Urine Collection: You will be asked to collect all urine samples over a 24-hour period and bring it back to the laboratory at your next scheduled visit. All supplies and instructions will be provided by study staff.

Pregnancy Test: If you are female, you will be required to have a pregnancy test. You will collect 2-3 teaspoons of your urine. If you are pregnant or the test indicates that you are pregnant, you will not be able to participate in this study. If you are a postmenopausal female who has not menstruated for at least 1 year, then you do not have to complete this test.

Body Weight and Composition: These tests are to measure your body weight and body fat. Your body weight and height will be measured on a digital scale. Then you will lie on a hospital-type bed and a small amount of x-ray will be passed through your body to determine the amount of bone, muscle, and fat in your body. This unit is called a DEXA scan. This test takes approximately 15 minutes and there is no pain associated with the procedure.

Session 4, 10, 13, 19: (Approximately 3 hours) Garvin Building, Suite 1575
Overnight Fast: You will be asked to avoid eating or drinking anything except water and to avoid consuming any caffeine-containing beverages for 12 hours prior to this visit so that the test results will not be influenced by the food you eat or by the normal digestion process.

Infection/Inflammation Questionnaire: You will be asked to complete a questionnaire about any recent illnesses or infections.

Blood Pressure and Heart Rate: You will be asked to rest quietly for 15 minutes. We will then

measure your resting blood pressure using a stethoscope and standard blood pressure cuff or an automatic blood pressure monitor. Your heart rate will also be determined by the monitor or by placing a sensor on your index finger.

Body Mass: Your body weight will be measured on a digital scale.

Dietary Intake Analysis (24-hour recall): You will be asked to recall all the food and beverages you consumed in the previous 24-hour period.

Mixed Meal Tolerance Test: One small plastic tube (catheter) will be placed in one of your arm veins. After a baseline blood draw, you will drink a mixed meal beverage, Ensure Plus®, and blood will be collected in small amounts (less than one half teaspoon) at five timepoints over a 2-hour period.

Continuous Glucose Monitoring: We will remove the device that was placed on your upper arm area 3-4 days ago.

****After Session 5 & 16:**
Choline Supplement/Placebo: You will be given enough capsules and asked to consume 1000 mg (2 x 500 mg) of choline or the placebo with a bottle of water every day for one week.

****After Session 10:**
Following this session, you will return to your normal activities for two weeks during the "washout" period.

Sessions 5-7; 14-16: (Approximately 30 minutes per session) Garvin Building, Suite 1575
Infection/Inflammation Questionnaire: You will be asked to complete a questionnaire about any recent illnesses or infections.

Blood Pressure and Heart Rate: You will be asked to rest quietly for 15 minutes. We will then measure your resting blood pressure using a stethoscope and standard blood pressure cuff or an automatic blood pressure monitor. Your heart rate will also be determined by the monitor or by placing a sensor on your index finger.

Choline Supplement/Placebo: You will be given enough capsules to last one week and asked to consume 1000 mg (2 x 500 mg tablets) of choline or the placebo with a bottle of water every day.

Body Mass: Your body weight will be measured on a digital scale.

Dietary intake analysis (24-hour recall): You will be asked to recall all the food and beverages you consumed in the previous 24-hour period.

What are my responsibilities if I take part in this research?

If you take part in this research, your responsibilities will be to:

- Provide an accurate history of any health problems or use of medications before the study begins.
- Inform the investigators of any discomfort or unusual feelings before, during or after any of the study sessions.
- Be on time and attend all scheduled visits.
- Follow all participant instructions for each session.
- Follow physical activity instructions provided by the investigators.

Clinically Relevant Results

If results of study procedures (e.g. blood tests, imaging scans) give clinical information that may be important to your health care, you will be told about those results.

Could being in this research hurt me?

Risks of Choline: Choline is a water-soluble vitamin-like essential nutrient that is available as an over the counter supplement. Tolerable upper intake level for adults is 3500 mg/day. Doses over the daily upper intake levels may cause side effects such as sweating, a fishy body odor, gastrointestinal distress, diarrhea, and vomiting. Some individuals might be allergic to choline or the other ingredients. The dose of 1000 mg in this study is well below the tolerable upper intake level in adults.

Catheter Blood Draw: Some pain or discomfort may be experienced when the catheter is inserted in the vein, but this should persist for only a short time. During the blood draws, you may have pain and/or bruising at the place on your arm where the blood is taken. In about 1 in 10, or 10%, of the cases, a small amount of bleeding under the skin will cause bruising. The risk of a blood clot forming in the vein is about 1 in 200, while the risk of infection or significant blood loss is 1 in 1000. There is a small risk of the vein becoming inflamed and/or painful in the hours or days after the needle is removed. If you feel faint during or after a blood draw, you should notify the study doctor or study staff immediately and lie down right away to avoid falling down. Having staff who are experienced in performing blood draws will reduce these risks.

Oral Glucose Tolerance: Because this procedure requires the placement of the catheter in a vein in one arm, the risks here are identical to those stated above. In addition, there is a small risk of low blood sugar occurring during or after the test. If this happens, orange juice (with table sugar) or some other-sugar containing food will be given to you.

HIV/AIDS and Hepatitis: In the event a researcher or other staff person is improperly exposed to your blood, your blood will be tested for the presence of HIV, the Hepatitis B Virus, and the Hepatitis C Virus. There will not be any cost to you for this test. The research team will follow proper procedures for testing and reporting as outlined by Virginia State Law, which includes sending the sample to a certified laboratory. Please note that, should your blood require testing, you will be informed of your test results and provided with the opportunity to receive appropriate and timely counseling. In addition, your results will be sent to the local health department.

DEXA Scan: The amount of radiation that you will receive in the DEXA exam is less than the amount permitted by the Food and Drug Administration (FDA) per year. The amount you will receive per scan is equal to 1/20 of a chest x-ray. The more radiation you receive over the course of your lifetime, the more likely your risk increases in developing cancerous tumors. The radiation in this study is not expected to greatly increase these risks; however, the exact increase in such risk is not known.

Arterial Stiffness: There is a risk of slight discomfort due to very slight pressure being applied to the carotid artery during the ultrasound procedure and to the carotid, brachial, radial, and femoral arteries during the tonometry procedure.

Endothelial Function: Some pain or discomfort may be experienced when the blood pressure cuff is inflated, and you may have discomfort/pain and/or bruising at the place on your arm where the cuff was inflated. However, the discomfort/pain is temporary and will resolve within a short time after completing or stopping the procedure.

Risks of Nitroglycerine: There is a small risk that you will become lightheaded, dizzy, or faint following nitroglycerin administration. You may get a headache, but this only lasts a few minutes. If you are taking Cialis or Viagra, you cannot participate in this aspect of the study.

Continuous Glucose Monitoring: The placement of the device will require a sensor being inserted into the back of your upper arm. When the sensor is placed by the researcher, you can expect a sensation similar to a needle insertion for a blood draw. You may experience some discomfort during the insertion, or pain, inflammation, redness, swelling, minor bleeding and/or minor infection at the site. This will all be minimized by having a trained individual to perform the procedure and will take place in aseptic conditions. You may also experience these symptoms as a result of contact between the adhesive pad of the sensor and the skin; allergic reactions can develop in response to the adhesive used to keep the device in place. If any of these symptoms occur, you have the ability to remove the device at will and the symptoms will clear up a short time later.

In addition to these risks, taking part in this research may harm you in unknown ways. It is not possible to identify all potential risks in an experimental study. However, the study doctor and study staff will take all possible safeguards to minimize any known and potential risks to your well-being. All of the procedures are well established and used routinely in the study investigator's laboratory. Side effects are possible in any research study despite high standards of

care and could occur through no fault of your own or the study doctor or study staff.

Will it cost me money to take part in this research?

Taking part in this research may lead to added costs to you, such as transportation. However, there will be minimal transportation to and from the study location, and we do not anticipate any additional uncompensated costs

Will being in this research benefit me?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include contributing to improving the understanding of how choline intake impacts health.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study product may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings, presentation reports, academic papers, or in publications; however, you will not be identified in these presentations and/ or publications.
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal

information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration
- Department of Health and Human Services agencies
- Governmental agencies in other countries
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Accrediting agencies
- Health insurers and payers

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at

any time. You do this by sending written notice to the study investigator at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

Notice Concerning HIV-Related Information: HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without your authorization, unless federal or state law requires the disclosure. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the agencies responsible for protecting your rights.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

What if I am injured because of taking part in this research?

If you are injured as a result of this study, you should seek medical care. Neither the researchers nor the University have money set aside to pay for medical treatment that would be necessary if you are injured as a result of your participation in this study. Any expenses that you incur, including emergencies and long-term expenses, would be your own responsibility. You should consider this limitation before you consider participating in this study.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- Lack of compliance to instructions
- Inability by the researchers to obtain measurements that are necessary for the study
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- You become pregnant
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

Your participation in this study is voluntary. You are free to withdraw from the study at any time for any reason. Simply inform the researchers of your intention to cease participation.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to a total of $400. Your compensation will be broken down as follows:

You will receive $20 each for testing sessions 2 through 18. After completing all aspects of the study, you will receive an additional $60 at session 19. There is no compensation for completing the first session.

Statement of Consent:

Your signature documents your consent to take part in this research.

_____

Printed Name of the Subject

_____ _____

Signature of adult subject capable of consent Date

_____ _____

Signature of person obtaining consent Date