Impact of Inflammation on Reward Circuits, Motivational Deficits and Negative Symptoms in Schizophrenia

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You Are Being Asked to Be in a Research Study

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 20 people who are being studied, at Grady Memorial Hospital and Emory University.

Why is this study being done?
This study is being done to answer the question: ***Do metabolic disturbances and inflammation contribute to negative symptoms of schizophrenia? You are being asked to take part in this study because, based on your lab results from participating in Part A, you may have metabolic syndrome. Metabolic syndrome will be determined by vital signs and lab values. It may contribute to insulin resistance and risk for diabetes.***

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate in 2 study visits. The researchers will ask you to do the following: Answer questions about your mental health, participate in a test for diabetes called an Oral Glucose Tolerance Test, have blood and urine tests to make sure you are healthy and 2 MRI scans. All of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study questions about whether insulin resistance impacts inflammation in patients with schizophrenia and whether insulin resistance and inflammation impact reward circuits and negative symptoms in patients with schizophrenia.

What are the risks or discomforts I should know about before making a decision?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include possible risks of the loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study

This study is completely voluntary. If you decide not to participate, you can still receive regular care from your regular doctor.

Costs

You WILL NOT have to pay for any of the study procedures, in particular, those that are not covered by your medical insurance.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to consider this and talk about it with your family and friends.

Emory University and Grady Health System
Consent to be a Research Subject / HIPAA Authorization

PART C

Title: **Impact of Inflammation on Reward Circuits, Motivational Deficits and Negative Symptoms in Schizophrenia**

Principal Investigator: [redacted] **MD**

Sponsor: National Institute of Mental Health (NIMH)

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

What is the purpose of this study?

This study will explore whether metabolic disturbances and inflammation contribute to the negative symptoms of schizophrenia. It will also look at the impact of insulin resistance on inflammation.

What will I be asked to do?

Twenty male and female participants who were enrolled in Part A of the study and found to have possible metabolic syndrome, will be invited to participate in this optional study. You will have an oral glucose tolerance test and MRI scans done. You will not be asked to take any new medications for this study. Including today's visit, your participation will last for 2 visits.

The study doctor and a member of the study team will ask you questions and run some tests to determine if you are eligible to enter the study. It is important that you answer all of the questions honestly and completely. If your condition or circumstances change during the study, you must tell the study doctor.

If you plan to take any new medications or undergo any new medical treatment, please let the study team know. This includes medications given to you or recommended by any other doctor. It also includes over-the-counter drugs such as cough or cold treatments, pain medications such as aspirin or ibuprofen, drugs/procedures from another study, and sleeping medications.

Study Procedures:

OGTT Screening Visit
The informed consent process and Screening visit will take place virtually (over the phone or a computer) or at one of the following sites; Grady Behavioral Health Clinic (Grady BHC), Emory University Hospital Georgia Clinical & Translational Science Alliance Clinical Research Center (EUH GCTSA GCRC), Woodruff Memorial Research Building (WMRB-PI Office Space) or at the Facility for Education and Research in Neuroscience (FERN) at Emory. If you agree to participate, you will be asked to do the following at today's visit following the informed consent. A study team member will ask you about the medications you are taking. You will be asked not to eat or drink anything after midnight the night before coming in. You will get blood drawn, vital signs checked and waist circumference measured to ensure you can be included in the study.

You will receive a urine drug screen test and a pregnancy test if you are a female. You will not be able to enter the study if you have a positive urine drug screen or a positive pregnancy test. If you are a woman of childbearing age we will ask you for documentation of adequate birth control during the study period.

You will be asked questions about your psychiatric history and symptoms. There will be an option for you to allow us to video-record and audio-record some of your answers to the questions about your mood and symptoms.

Today's visit will take approximately 2-3 hours. If you qualify for the study and choose to enroll, you will participate in 1 more study visit that will take place at Emory University.

OGTT Visit 1
This visit will occur at Emory University Hospital (GCRC) and FERN. On the night before OGTT Visit 1, you will be asked to not eat or drink anything (except water) after midnight so that the nurse can get a fasting blood sample. A study team member will call you to remind you of this. Lunch will be provided at this visit.

You will be provided transportation to Emory University Hospital where you will complete routine blood and urine lab work checking for signs of infection. You will also be asked to give a urine sample to test for the presence of drugs in your body. You must have a clean urine drug screen to participate in this visit.

If you are a woman, you will receive a pregnancy test. If you are pregnant, you will not be able to participate in the study.

If you agree, we may send part or all of your urine sample to a laboratory at Emory to conduct some further tests. The researchers in this lab may take the cells from your urine to create something called induced pluripotent stem cells (iPSC). This type of cell can be used to create different types of tissue, including cells found in the brain called neurons. Your cells might be used in research involving genetic alterations of the cells.

Your urine sample may be used to create a living tissue sample (called a "cell line") that can be grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you. Your cells may be mixed with other human cells, mixed with animal cells, or grown in lab animals like mice.

What you should know about the cell lines that will be derived in the course of this study:

- The cell lines created will be similar or identical to you genetically.
- The cell lines may be kept indefinitely.
- There is the possibility that your cells or the created cell lines might be used in research that will involve genetic manipulation of the cells or the mixing of human and non-human cells in the animal models.
- The cell lines may be shared with researchers both inside and outside of Emory University, including commercial partners.

The cell lines may be used to develop treatments for a variety of disease and conditions.

At this visit, a nurse will check your vital signs, measure your waist circumference and draw blood to test. You will then get the Oral Glucose Tolerance Test. For this test, you will drink a solution containing sugar so that we can check your blood sugar level. You will get your blood drawn once before drinking the solution and up to three times after drinking the solution.

You will be asked questions about your mental health and play a computer task before and after the OGTT. You will then participate in up to two sessions of MRI scans, like those performed in part A of the study. These will be conducted using the same MRI scanner as you participated in before.

You will lie down in the MRI scanner. You will be asked to sit silently part of the time and for the rest of the time in the scanner you will be making decisions about the computer game.

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study. If you choose to withdraw, you may request that any blood samples or data already collected be destroyed or no longer used. If you choose to do this, you must contact the Principal Investigator of the study, Dr. David Goldsmith.

Risks

Blood Draws: Collecting blood from a vein in someone's arm is a standard medical procedure, although sometimes there may be some minor pain or bruising. Fainting and infection at the site of the blood draw are also known risks. Because we will be looking at biochemical information in your blood, there may also be other risks that we currently don't recognize or expect. Results that are considered important for your safety such as signs of infection, changes in blood glucose or electrolyte concentrations will be provided to you or your doctor, after obtaining a consent from you by obtaining your signature on a form for release of information. The research information that is learned from studies of your samples may be used scientifically and may be used by the sponsor in other research. The results of the analysis of your samples will not be made available to you. A research lab, not an

Emory or Grady Healthcare lab, will do the testing. Some samples may be sent to other labs for additional analysis. The results of the biochemical analysis will not be recorded in your medical record. As for the blood drawing, standard sterile procedure for blood withdrawal will be used. In addition, the volume of blood withdrawn for the study will not exceed 200ml (about 13 tablespoons).

In addition, we will ask you to allow us to measure a genetic substance in your blood called messenger RNA (mRNA). We will NOT be collecting any DNA from your blood. This RNA testing is optional, and you may choose not to participate in this part of the study if you'd like. If you choose to participate in this portion of the study, please see the section "Optional Study: Genetic Testing of Blood Samples" below.

Psychiatric Assessments: You may experience psychological or emotional discomfort when asked questions about your symptoms during each study visit. The questions involve no specific risks or discomforts beyond those of standard clinical interviews. This includes possibly feeling upset when talking about your current or past psychiatric symptoms. There may be questions that may cause you to feel uncomfortable. If you do not wish to answer any questions, you are not required to do so. Your participation is voluntary.

Serious mental illnesses, such as schizophrenia and depression, are the most important causes of suicidal thoughts or actions. During treatment of schizophrenia, suicidal thoughts or behaviors can be observed in patients, even when they are taking medications. If you have suicidal thoughts, with or without suicidal behavior, at any point during the study, you must tell your doctor right away.

You may also find that the computer tasks are boring and may make you feel tired. Some tasks may also require some rapid button pressing, which could lead to mild discomfort in the hands.

MRI Scan

Another common risk is associated with the MRI. The MRI uses magnetic fields which have been found to be safe to use by the Food and Drug Administration (FDA). The scanner can be loud. You will be given earplugs and headphones to lower the noise of the MRI machine. You may also have some muscle discomfort in the scanner. You may also feel too hot or cold. If this is the case, you may ask for a blanket. You may also feel claustrophobic or a sense of dizziness while in the scanner. If this happens and you feel uncomfortable, you may ask to be taken out of the scanner immediately.

If you are a woman: to protect against possible side effects, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. There may be some risks with MRI scanning to the developing fetus, especially in early pregnancy. There may also be other unknown risks. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is designed to learn more about the effects of metabolic syndrome and inflammation on certain symptoms of schizophrenia. While this study is not designed to benefit you directly, it may be used to help others in the future.

Will I be compensated for my time and effort?

You will be compensated up to $175 for your participation in this study. Each of your visits will be compensated according to the schedule below.

Screening Visit: You will be compensated $25 for the screening visit. You must pass a urine drug screen test to receive compensation for this visit. If the urine drug screen shows that you have illicit drugs in your system, you will not receive any compensation.

OGTT Visit 1: You will receive up to $150 for participation in this study visit.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. Someone from the study team will discuss these with you. You do not have to be in this study to be treated for schizophrenia.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory University and Grady Health System will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from sharing the following information about you:

1. Giving state public health officials information about certain infectious diseases,
2. Giving law officials information about abuse of a child, elderly person or disabled person.
3. Giving out information to prevent harm to you or others.
4. Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study, including your de-identified genetic information, may be shared with the research community at large to advance science and health. Data from this study may be placed into

public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Genetic Information

How is my Genetic Information Protected? What are the Risks?
The Genetic Information Nondiscrimination Act (GINA) is a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, Medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers' compensation equivalent coverage, or other similar limited accident and sickness policies.

Privilege
In the State of Georgia, your genetic information has special legal protections called "privilege," which means that the information cannot be used as evidence in a court. By signing this form and allowing us to use and disclose your genetic information for the purposes described in this consent, you waive any privilege with regard to that genetic information, meaning that the information loses this legal protection.

Incidental Findings from Imaging Tests and Scans (e.g. fMRI)
You will be getting a scan for research purposes only. The research does not require health professionals to read the scan. The researchers are not qualified to interpret the images for healthcare purposes. Do not rely on the scan for clinical or diagnostic purposes. However, if the researchers have a question about something they see on the scan they will tell you. They will ask you if you want the scan sent to a qualified health professional for review and any further medical treatment. You or your insurance company may have to pay for the review and any such treatment.

Medical Record

If you have been an Emory and Grady Health System patient before, then you already have an Emory and Grady Health System medical record. If you have never been an Emory and Grady Health System patient, you do not have one. An Emory and Grady Health System medical record will be made for you if an Emory and Grady Health System provider or facility gives you any services or procedures for this study.

We will take reasonable steps to keep copies of this form out of Emory and Grady Health System's medical records system. If we aren't successful in keeping these forms out, despite our efforts, we will take steps to remove them. If they cannot be removed, we will take steps to limit access to them.

Emory and Grady Health System may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Grady Health System medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will ***not*** be placed in your medical record. For this study, those items include: Cognitive tests results, self-report forms, clinician administered evaluations, MRI scans and biological samples (blood and urine) collected for research purposes.

Tests and procedures done at non-Emory and Grady Health System places may not become part of your Emory and Grady Health System medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you get ill or injured from being in the study, Emory and Grady Health System will help you get medical treatment. Emory and Grady Health System and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory and Grady Health System or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. [redacted] at telephone number [redacted]

You should also let any health care provider who treats you know that you are in a research study.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study
You have the right to leave this study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

No Provision of Treatment
There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose (Share) Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Grady Health System may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- National Institute of Mental Health (NIMH) is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Grady Health System offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Grady Research Oversight Committee, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Optional Study: Genetic Testing of Blood and Urine Samples

PHI That Will be Used/Disclosed for Optional Study:
The PHI that we will use and/or disclose (share) for the optional research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for which your PHI will be Used/Disclosed for Optional Study:
We will use and disclose your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Expiration of Your Authorization
Your PHI will be used until this research study ends and all data has been analyzed.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Dr. [redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.
To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Other Items You Should Know
Dr. [redacted], one of the study team doctors, is a co-inventor of the EEfRT task software, which is used in this study. Emory University and Vanderbilt University licensed this software to BlackThorn Therapeutics. Under the policies of both universities, Dr. [redacted] receives licensing fees and royalties from BlackThorn Therapeutics. Additionally, Dr. [redacted] has a paid consulting relationship with BlackThorn. The terms of this arrangement have been reviewed and approved by Emory University in accordance with its conflict of interest policies.

<u>Contact Information</u>
Contact Dr. [redacted] at [redacted]

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory University Institutional Review Board at [redacted] or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you feel you have had a research-related injury or
- if you have questions, concerns or complaints about the research.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

Consent and Authorization

Consent and HIPAA Authorization for Optional Study/Studies:
Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study/studies previously described:

[Genetic Testing of Blood Samples] _____Initials ☐ I Agree ☐ I Do Not Agree

[Genetic Testing of Urine Sample] _____ Initial ☐ I Agree ☐ I Do Not Agree

[Audio Recording of some questions] _____Initials ☐ I Agree ☐ I Do Not Agree

[Video Recording of some questions] _____Initials ☐ I Agree ☐ I Do Not Agree

TO BE FILLED OUT BY PARTICIPANT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Participant

_____ _____
Signature of Participant (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**