# STIM Alzheimer's Disease PET Disclosure

# NCT04818255

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# UNIVERSITY OF MICHIGAN

# CONSENT TO BE PART OF A RESEARCH STUDY

## 1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

**Study title:**

STIM Alzheimer's Disease PET Disclosure

**Study Short Title:**

STIM+ Part II

**Company or agency sponsoring the study:**

National Institute on Aging/National Institutes of Health

**Names, degrees, and affiliations of the principal investigator:**

Principal Investigator: Benjamin Hampstead, Ph.D., ABPP/CN, Department of Psychiatry, University of Michigan

Co-Investigators: Annalise Rahman-Filipiak, Ph.D., Department of Psychiatry, University of Michigan and J. Scott Roberts, Ph.D., School of Public Health, University of Michigan

### 1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

Participants will be eligible to learn about their risk for Alzheimer's disease (AD) and Dementia – Alzheimer's Type based on personal health information collected in the prior research . All participants must have already completed education and decision-making assessment through the STIM+ Education & Decision-Making study. If participants are eligible and choose to receive their personal risk estimate, we will assess participant and study partner understanding of and reactions to the information you learn today in two follow-up visits.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include increased anxiety or worry if one or more of your partner's personal health indicators suggest he/she has indicators of Alzheimer's disease in his/her brain. Additionally, there may be a risk of insurance discrimination or denial if your partner chooses to share the information you learn in this study with his/her medical providers or others. More detailed information will be provided later in this document.

This study may offer some benefit to you now or in the future by increasing your awareness of your partner's risk for DAT, allowing for planning of future medical, financial, and personal decisions. Additionally, this study may benefit others by allowing researchers to better understand how to share DAT risk information with older adults

and their loved ones in a way that helps them to comprehend and use the information effectively when making decisions about their health in the future. More information will be provided later in this document.

We expect the amount of time you and your partner (the study participant) will participate in the study will be about 3.5 hours across three sessions.

You can decide not to be in this study for any reason. Choosing not to be in the study will not affect the healthcare you receive in any way. The only alternative to the study is to simply not take part. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues below.

## 2. PURPOSE OF THIS STUDY

### 2.1 Study purpose:

Dementia is defined by a loss of cognitive (thinking) abilities and difficulty functioning in your everyday life. Dementia can be caused by several diseases, with Alzheimer's disease (AD) being the most common of these causes. When dementia is caused by AD, we refer to it as dementia of the Alzheimer's Type (DAT). The greatest risk factor for Alzheimer's Disease (AD) and DAT is advancing age, but DAT is not a normal part of aging. Studies have shown that changes in the brain happen before full symptoms of DAT develop. These changes include a buildup of two proteins within the brain, called amyloid and tau.

The purpose of this study is to learn about the best ways to communicate information about personal amyloid and tau status and AD.

## 3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

### 3.1 Who can take part in this study?

Participant Eligibility: All participants who enroll in this study must also have previously taken part in a study through the Research Program on Cognition & Neuromodulation Based Interventions (Stimulation to Improve Memory, Brain-Behavior Characterization) or through the Michigan Alzheimer's Disease Research Center (Driving & Physiological Responses, Dementia in African American Population Phenotyping from Potential Elevated Risk) that involved PET scans for Alzheimer's disease markers. They must also have available data amyloid or tau from positron emission tomography (PET) imaging, from the previous study. Participants with a diagnosis of Mild Cognitive Impairment are encouraged to bring a study partner such as a family member or trusted friend to the session. Participants diagnosed with Dementia – Alzheimer's Type must be accompanied to the session by at least one study partner (e.g., family member or trusted friend). If the participant has a legally authorized representative (LAR) or durable power of attorney (DPOA) for research and/or medical decisions, this individual must serve as the study partner and attend all sessions.

Participants must also have completed all study activities included in STIM+ Part I, including screening, the educational module about AD/DAT, and an assessment of decision-making capacity. Study team members will determine the participant's and study partner's eligibility to take part in STIM+ Part II based on this information. Additional inclusion and exclusion criteria are listed below:

Participant Inclusion Criteria:

- Completed all portions of previous study.
- If diagnosed with DAT, the participant must bring a study partner (e.g., family member or trusted friend) to the disclosure session.

- If the participant has a designated LAR/DPOA for medical and/or research decisions, that individuals must serve as the study partner and be present at the disclosure session.
- Participant or study partner demonstrates decision-making capacity to engage in PET disclosure, as determined in STIM+ Part I.

Participant Exclusion Criteria:

- Active diagnosis of depression or anxiety disorder
- Newly diagnosed (since completion of previous study) neurologic injury or disease

Study Partner Inclusion Criteria:

- Study partners are those who are currently serving as a caregiver to the participant, or would hypothetically serve in this role should the need arise
- Must have known the study participant for at least five years
- Must be in contact with the study participant (any modality) at least once per week
- Cognitively healthy
- 18 years or older
- English speaker

Study Partner Exclusion Criteria:

- Has a diagnosis of cognitive impairment or dementia
- Does not demonstrate decision-making capacity

**3.2 How many people are expected to take part in this study?**

Approximately 100 participants and their study partners, as applicable, are expected to participate.

## 4. INFORMATION ABOUT STUDY PARTICIPATION

**4.1 What will happen to me in this study?**

You and your partner (i.e., the participant) will attend your appointment either in person or via video-conference using a HIPAA-compliant, secure platform (Zoom for Health), based on your preference and current University of Michigan guidance around Covid-19 safety. If you choose to complete your session in person, you must comply with all safety screenings and procedures, as will all study team members. If you choose to complete the session via video-conference, the session will be video-recorded to ensure that the study team are able to fully capture your responses.

PET Disclosure: Participants and study partners will complete an Emergency Contact Information sheet. You will be asked to list two personal emergency contacts and one physician contact. In the event that your partner experiences significant study-related distress, the study team may disclose to one of these emergency contacts, or to emergency medical services, that your partner is enrolled in this study; however, their personal risk results will not be disclosed by the study team. In the event that you experience significant study-related distress, the study team may disclose to one of your emergency contacts, or to emergency medical services, that you are enrolled as a study partner in this study

Study team members will then share whether your partner's PET scan results indicate significant amounts of amyloid and tau proteins in his/her brain. We will discuss the meaning of these indicators in relation to whether your partner has Alzheimer's disease, and time will be allotted for any questions you may have.

Possible results are summarized in the table below:

| Indicator | Negative Result | Positive Result |
|---|---|---|
| **Amyloid Protein** | "Not elevated" brain protein | "Elevated" brain protein |
| **Tau Protein** | "Not elevated" brain protein | "Elevated" brain protein |

- Having elevated amyloid, regardless of the participant's tau results, would mean they have evidence of Alzheimer's disease in their brain. Amyloid and tau together may suggest a more advanced stage of Alzheimer's disease.
- Having a negative amyloid result would mean they do not have evidence of Alzheimer's disease in their brain, regardless of your tau results.
- Having Alzheimer's disease is different than having Dementia – Alzheimer's Type. Not everyone with AD (e.g., amyloid and tau positivity) will go on to develop DAT.
- The results from PET scanning may change over time. This means that your partner may be negative at this time, but positive in the future.

Directly after PET disclosure, you and the study participant will be asked to complete questionnaires evaluating both of your reactions to this information. The PET disclosure session will be video recorded.

Follow-Up Phone Calls: Participants and study partners who receive PET disclosure will complete a brief follow-up visit via phone within 1-week and at 6-weeks following your initial visit. The study research associate will call you to complete questionnaires on your reactions to learning your partner's personal health information. Each of these visits should take 30-60 minutes. The study social worker, who is also a licensed and trained clinical provider, will be available to you and the study participant between these visits to provide additional support or assist you with finding resources if needed. In addition to the 1- and 6-week formal follow-up visits, the social worker may call you to see if you need additional resources or support between sessions.

As a study partner co-participating in this research study with the participant, you have certain responsibilities, such as ensuring that you and the study participant attend your scheduled appointment and report any adverse reactions you may have during this study.**4.2 How much of my time will be needed to take part in this study?**

Participants and their study partner (e.g., family member, trusted friend, LAR/DPOA) will complete a 90-minute disclosure session via video conference. Participants and study partners will then complete an additional two 30-to-60-minute phone sessions for follow-up, within 1 week and at 6 weeks after your initial appointment. Though additional check-in calls may be made by the social worker to ensure you and your partner feel supported, these are for your benefit as needed, and not required for participation. Therefore, the maximum time you will commit to this study is 3.5 hours.

**4.3 When will my participation in the study be over?**

Study participation will be over after completion of your second follow-up session, approximately 6 weeks following your first session.

**4.4 What will happen with my information and/or biospecimens used in this study?**

Your partner's biospecimens and collected information may be shared with the National Institute on Aging/National Institutes of Health.

With appropriate permissions, your partner's biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies.

Your partner's identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

## 5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

### 5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Questionnaires: The study questionnaires are entirely non-invasive and painless.

Psychological Distress: It is possible that you and your partner will find out that your partner has positive indicators for AD, which may increase your partner's risk for developing the disease in the future. As a result, you and your partner may experience some increased worry, sadness, or frustration about the future. Researchers will try to minimize these risks by providing you with educational materials, an action plan, and support resources. Researchers will also assess your thoughts and feelings after disclosure and offer follow-up debriefing and referral to mental health and other providers if requested, or in the case of a mental health emergency. If you become so upset that you cannot continue, you may ask to be withdrawn from the study. In this case, the research team will work with you to identify support as requested, but you will no longer participate and no additional study data will be acquired from you.

Brain Protein Results: Some medical information, such as genetic testing results, is protected by federal law to ensure that it cannot be used against you in the future. For instance, the Genetic Information Non-Disclosure Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. In other words, GINA stops these companies from denying you health/long-term care insurance, asking you to pay more for this insurance, or denying you employment based on an identified genetic disorder.

GINA and other laws do not provide protection against discrimination based on the results from amyloid and tau PET scans. While we will not release your partner's results to any individual or organization without his/her request and approval, he/she may decide that they want the results shared with his/her medical providers. If your partner chooses this option, there is the possibility that his/her doctor may add the information to his/her medical record, making it accessible to health insurance companies. If this were to happen, there is a possibility of discrimination based on this information, including denial, restrictions, or increased costs of health, disability, and long-term care insurance, or negative impacts for employment.

Confidentiality: Although unlikely, there may be a risk of breach of confidentiality or privacy. We minimize this risk by assigning participants and study partners an ID number that is used to collect and store your data in place of any personal identifiable information (e.g., your name, contact information). See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

### 5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

**5.3 If I take part in this study, can I also participate in other studies?**

*Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies*. You should not take part in more than one study without approval from the researchers involved in each study.

**5.4 How could I benefit if I take part in this study? How could others benefit?**

You may benefit from learning whether your partner has Alzheimer's disease pathology in his/her brain. This information may assist you and your partner in making medical, social, and other important decisions in the future (e.g., about medical care, placement, estate planning). Finally, the information provided may give you peace of mind and reduce worry or confusion about your partner's health and symptoms. In addition to the potential benefits, others may benefit from the knowledge gained in this study.

**5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?**

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

## 6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

**6.1 If I decide not to take part in this study, what other options do I have?**

If either the participant or their study partner decide that they are no longer interested in participating in the study, they may choose to halt participation at any time. If your partner has already received your personal AD information, the study team will work with you to ensure that you and your partner have adequate support and resources, but you will not be asked to take part in any further study activities.

## 7. ENDING THE STUDY

**7.1 If I want to stop participating in the study, what should I do?**

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

**7.2 Could there be any harm to me if I decide to leave the study before it is finished?**

There will be no harm to the participant or study partner if you decide to leave the study before completion.

**7.3 Could the researchers take me out of the study even if I want to continue to participate?**

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- The researcher believes it is not in your partner's best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

## 8. FINANCIAL INFORMATION

### 8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study. The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study, call Dr. Rahman-Filipiak immediately, at (734) 936-3180. The doctor will either treat you or send you to another doctor for treatment. You will get free medical care for any complication, injury, or illness caused by the study procedure. The study sponsor and the study doctor are responsible for determining whether your condition was the result of your participation in the study. The study sponsor will pay for your treatment only if the need for treatment has been caused by the study procedure. This means that you or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

### 8.2 Will I be paid or given anything for taking part in this study?

The participant and study partner will each receive $20 for completing the disclosure session and $10 for each follow-up session (at 1-week post-disclosure and 6-weeks post-disclosure), for a maximum of $40 per person. You will receive your incentive as a check mailed to you after your participation is finished.

### 8.3 Who could profit or financially benefit from the study results?

None of the study team members, nor any organizations with which they are affiliated, have a financial interest in the outcome of this study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

## 9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

### 9.1 How will the researchers protect my information?

We will keep information collected from you and about you strictly confidential, including any research records we create, to the extent required by law. A breach of confidentiality of your personal, identifiable health-related information is extremely unlikely given measures taken to protect this information. Upon enrollment into the study, participants and study partners will each be assigned a unique alphanumeric ID number, which will be used on all study documentation. The exception is this consent form, which will be stored in a folder separate from your study data. Your name, date of birth, address, or contact information will not be included on any study forms. The electronic file linking your name to your unique identifier, as well as other electronic databases containing de-identified study data, will be password protected and stored on a secure electronic drive. Paper copies of your data will be stored in a locked filing cabinet, in a locked office that can only be accessed by study team staff.

For all sessions, the study team will send you and your partner a secure link to sign this form and to join the appointment through your email. All sessions will be completed using University of Michigan Zoom for Health, a HIPAA-compliant, secure video conferencing systems. It is possible that other secure video platforms may be used by the University of Michigan in the future. Only individuals with the unique link sent to you will be able to access the meeting, and protections are in place to ensure that no one else can join or see data from the meeting.

None of the results from your partner's study participation or your participation will be included in your medical record; however, a scanned, signed copy of this Informed Consent form will be uploaded into your medical record

to indicate that you have participated in this research study. This step allows your medical providers to know what research studies you have been involved in, so that they may contact the study team with questions related to your clinical care, if needed. If you wish to have any information from this study shared with your medical providers, you will need to request it and sign documentation to specify to whom the information will be given, what information should be provided, and for how long.

**Certificate of Confidentiality**

This research will be covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child or adult abuse and neglect, or harm to self or others. If you tell us or we learn something that makes us believe that you or others have been or may be harmed, we may be required to report that information to the appropriate agencies.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

**ClinicalTrials.Gov**

As required by U.S. law, this trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?**

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:

  - Make sure the study is done safely and properly
  - Learn more about side effects
  - Analyze the results of the study
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

**9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?**

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

**9.4 When does my permission to use my PHI expire?**

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

## 10. CONTACT INFORMATION

**10.1 Who can I contact about this study?**

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

**Principal Investigator:** **Benjamin Hampstead, Ph.D., ABPP/CN**
Mailing Address: Arbor Lakes 1,
4251 Plymouth Road, Suite 2400, Ann Arbor, MI 48105
Telephone: (734) 936-6185

**Study Coordinator:** **Annalise Rahman-Filipiak, Ph.D.**
Mailing Address: Arbor Lakes 1,
4251 Plymouth Road, Suite 2400, Ann Arbor, MI 48105
Telephone: (734) 936-3180

**Study Social Worker:** **Marie Milliken, LMSW**
Mailing Address: Geriatric Center Clinics
4260 Plymouth Rd, Ann Arbor, MI 48109
Telephone: (734)763-6701

**You may also express a question or concern about a study by contacting the Institutional Review Board listed below:**

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

*When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

## 11. RECORD OF INFORMATION PROVIDED

### 11.1 What documents will be given to me?

Your signature in the next section means that you have received a signed and dated copy of the following document:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.*

## 12. SIGNATURES

**Consent/Assent to be contacted about Future Research**
I wish to be contacted about other research studies for which I may qualify.

Yes ☐ No ☐ Initial: _____ Date: _____

**Consent to Participate in the Research Study**
I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

**Consent to video recording solely for purposes of this research**
This study involves video recording. If you do not agree to be recorded, you CANNOT take part in the study.

_____ Yes, I agree to be video recorded.

_____ No, I do not agree to be video recorded.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

**Principal Investigator or Designee**

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____