ID: HUM00178869

SHARE(D) Stage II: Alzheimer's Risk Disclosure Protocol Piloting

NCT04309500

01/26/2022

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:

Development of Culturally-Sensitive and Patient-Centered Feedback for Alzheimer's Dementia Risk Disclosure (Stage II)

Short Title:

SHARED Stage II

Company or agency sponsoring the study:

National Institute on Aging/National Institutes of Health

Names, degrees, and affiliations of the principal investigator:

Annalise Rahman-Filipiak, PhD, Department of Psychiatry, University of Michigan Medical School

1.1 Key Study Information

You may be eligible to take part in a research study as a study partner. 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 child care, 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 Dementia-Alzheimer's Type (DAT) based on personal health information collected in prior research studies through the Michigan Alzheimer's Disease Research Center, including Stage I of the Sharing Alzheimer's Risk Estimates in Diverse Populations (SHARED) study. As a study partner, you will accompany your study partner to all appointments. You and the participant will first see a brief educational presentation on the benefits and risks of learning about risk for DAT based on recent cognitive performance, genotype, the size of different brain regions, and/or levels of Alzheimer's-related proteins in the brain. Participants will then be asked if they wish to receive their personal risk feedback. Participants who wish to know about their risk will undergo an assessment to be sure they understand this decision prior to the study team determining if can share this information with them. You may also be asked to assist in making this decision, and asked questions to be sure you understand the risks and benefits of DAT risk feedback. If you and the participant are eligible and choose to receive the participant's personal risk estimate for DAT, we will show you a personalized presentation about the participant's risk for DAT. After this presentation, the study team will ask you questions to see how well you and the participant understood this risk information. We will also ask for your reactions to this information. We will ask you these questions immediately after the presentation, and at two follow-up visits a few weeks after the presentation.

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 personal health indicators suggest that your loved one is at increased risk for AD/DAT. Additionally, there may be a small risk of insurance discrimination or denial for your loved one if they choose to share their risk information with their medical providers or others. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by increasing your loved one's awareness of their risk for AD/DAT, allowing for both of you to better plan future medical, financial, and personal decisions. Additionally, this study may benefit others by allowing researchers to better understand how to share AD/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 will participate in the study will be up to 5 hours across three sessions.

You can decide not to be in this study. 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 – Alzheimer's Type (DAT) is the most common form of dementia. The greatest risk factor for 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 include changes in performance on tests of thinking abilities, decreases in the volume of certain areas of the brain, and a buildup of two proteins within the brain, called amyloid and tau. Additionally, your loved one may be able to be tested for a particular gene, called apolipoprotein-E (APO-E) that scientists believe increases your risk for DAT. All of these factors play a key role in the development and severity of DAT.

The purpose of this study is to learn about the best ways to communicate educational information about these factors, as well as personal risk information about the chance of developing DAT.

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?

'Participants' are those who will be eligible to receive feedback about their personal risk for DAT. 'Study partners' (you) are close friends or family members who know the participant well, and may as the participant's caregiver currently or in the future, if the need arises. You will not receive feedback about your personal risk for DAT, but will be present during the participant's feedback and asked about your understanding, reactions, and satisfaction.

Participant Eligibility: All participants must also have previously taken part in Stage I of the SHARED study. They must also have available data regarding cognitive test performance, amyloid or tau imaging, or structural neuroimaging from current or prior participation in the University of Michigan Memory and Aging Project (UM-MAP), Stimulation to Improve Memory (STIM), or Dementia in African American Population Phenotyping from Potential Elevated Risk (DAPPER) study. Participants must have been diagnosed as either cognitively normal or with Mild Cognitive Impairment via their UM-MAP or other recent neuropsychological evaluation (within the past 18 months). All participants must be accompanied to the session by you, the study partner. If the participant has a legally authorized representative (LAR) or power of attorney for research and/or medical decisions, that person must serve as the study partner. Additional inclusion and exclusion criteria for participants are listed below:

Inclusion Criteria:

- 65 years or older
- Diagnosed as either cognitively healthy or with mild cognitive impairment
- Non-Hispanic White or Black/African-American race/ethnicity
- Adequate hearing and vision (corrected or uncorrected)

Exclusion Criteria:

- Current diagnosis of significant depression or anxiety disorder
- History of severe mental illness (i.e., bipolar disorder, thought disorder, psychosis)
- Current/past significant substance use disorder
- History of major neurological disease (i.e., Huntington's disease, Parkinson's disease, seizure disorder, motor or gait abnormalities indicative of a neurologic diagnosis other than Alzheimer's disease)
- History of major neurological injury (e.g., moderate-to-severe head injury, stroke)

Study Partner Eligibility: You must be 18 years or older and cognitively healthy based on either recent evaluation (within last 18 months) or cognitive screening. If you have a history of severe mental illness, substance use disorder, or neurologic disorder, you will not be eligible to participate in the study. You must have known the participant for at least five years and have at least weekly phone, video, social media, or in-person contact with the participant. You must be the participant's current identified caregiver, or someone who is likely to serve in a caregiving capacity for the participant should the need arise in the future. Of note, if the participant has a legally authorized representative (LAR) or power or attorney (POA) for medical decisions or research, that person must be the study partner in this study.

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

10 participant-study partner pairs (20 people total) are expected to participate. Given the importance of understanding how findings from this study can be generalized to a diverse population of older adults, 5 of these participants in these pairs will be Non-Hispanic Black/African-American older adults, and 5 will be Non-Hispanic White older adults.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Screening and Consent: All study partners and participants will be screened via phone to ensure that you are both eligible for this study. If you are the LAR/POA for medical decisions and/or research, you will be asked to provide documentation prior to enrollment in the study.

If you and the participant are eligible, you will complete a video or phone call with a study team member to review the study procedures, risks and benefits in detail, and to sign the informed consent document (this form).

Study Session: You will attend your appointment either in person or via video-conference using a HIPAA-compliant, secure platform (University of Michigan 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.

The study session will include an educational presentation, and decision-making assessment. If the participant is eligible, it may also include feedback about his or her risk and follow-up questionnaires. This session will be recorded via video and will take up to 3 hours.

Education: The study team will show you a brief educational presentation about three topics: (1) DAT; (2) indicators for elevated DAT risk that may be present before a person could be diagnosed; and (3) risks and benefits of learning your personal DAT risk information.

Decision-Making Assessment: It is very important that you and the participant understand the risks and benefits of learning their risk for DAT. After the presentation, the study team will ask questions to determine how well you and the participant understand the information covered. If the participant (or you, as their study partner) is able to demonstrate that you fully comprehend this decision and interested in receiving this information, we will share the participant's personal DAT risk information with both of you. Please note that, if you want the participant to receive their risk information, but the participant declines to know this information, we will not move forward with disclosure. **If neither you nor the participant are able to fully comprehend the risks and benefits of receiving this information, the study team may decide not to proceed with risk disclosure. Therefore, it is not guaranteed that the participant will receive personal DAT indicator information as part of this study.**

Risk Feedback: Before sharing any information with either of you, the study team will ask the participant to complete an Emergency Contact Information sheet. In the event that they experience significant study-related distress, the study team may disclose to one of these emergency contacts, or to emergency medical services, that they are enrolled in this study; however, their personal risk results will not be disclosed by the study team.

Study team members will then present a summary of the participant's personal health data, including cognitive test performance, the size of different brain regions compared to peers, APOE genetic status, and/or the presence of Alzheimer's proteins in his/her brain. We will talk about what each of these indicators means, and whether the indicator suggests that the participant is at increased risk for DAT.

Possible results are summarized in the table below:

Indicator	**Negative Result** (does not indicate increased risk for DAT at this time)	**Positive Result** (***may*** indicate increased risk for DAT at this time)
Cognitive Testing	Normal scores for age and education	Scores below those expected for age and education
APO-E Genotype	Negative for e4 allele	Positive for e4 allele (1 or 2 copies)
Structural Brain Imaging	Normal brain volumes for age	Decreased brain volumes for age
Amyloid & Tau Proteins	"Not elevated" brain protein	"Elevated" brain protein

- There is no single indicator that can determine if the participant will develop DAT.
- A positive result on any or all five indicators does not mean that the participant will develop DAT.
- With the exception of APO-E genotype, the results from each of these indicators may change over time. This means that the participant may be negative at this time, but positive in the future.

Directly after risk disclosure, you and the participant will be asked to complete questionnaires evaluating your reactions to this information.

Follow-Up Calls: If you and the participant and study partners receive risk feedback, you will complete a brief follow-up visit via phone or video 1-week and 6-weeks following your initial visit. You will not need to visit us in person for these follow-up sessions. A study team member will help you complete questionnaires about your reactions to learning the participant's personal health information. Each of these visits should take 30-60 minutes.

As a subject participating in this research study, you have certain responsibilities, such as ensuring that you attend your scheduled appointment and reporting any adverse reactions you may have during this study.

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data and/or biospecimens. We would also like your permission to keep some of your questionnaire responses and medical information collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep your questionnaire response data and medical information for future research.

If you give us your permission, we will use your questionnaire responses and medical information for future research. Even if you give us permission now to keep some of your data and medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your data, we may not be able to take the information out of our research.

We may share your data and medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your data and medical information with other researchers, we will not be able to get it back.

There are no risks the future research may pose with the sharing of your questionnaire responses. There are some risks explained in section 5 that may apply to sharing medical information. More detailed information will be provided later in this document on how the study team will protect your confidentiality and privacy.

Future use of your identifiable data will be conducted in compliance with applicable regulatory requirements. Allowing us to share your medical information will not benefit you directly.

You will not find out the results of future research on your questionnaire responses. Allowing us to do future research on your data and medical information will not benefit you directly.

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

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

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.

4.2 How much of my time will be needed to take part in this study?

You and the participant will complete a single 3-hour education and risk disclosure session. If you and the participant receive risk feedback, you will then complete an additional two 30-to-60-minute sessions for follow-up, 1 week and 6 weeks after your initial appointment.

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

With appropriate permissions, your 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 educational materials and questionnaires are entirely non-invasive and painless.

Psychological Distress: Participants/study partners who cannot demonstrate decisional capacity for risk disclosure after the educational presentation will not receive this information. This decision is up to the study team and based on a set of objective criteria to protect potentially vulnerable participants and study partners from engaging in a health decision without fully appreciating the risks and benefits. However, if this does occur, you may feel frustrated or disappointed.

If the participant does receive risk feedback, it is possible that you will find out that your loved one is at risk for DAT. As a result, you and your loved one 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 risk 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 further study information will be collected.

There are additional risks that may apply to your study partner, the participant, because they are the one's receiving personal risk information:

Genetic Results: The federal Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against any individual based on their genetic information. Under this law:

- Health insurance companies and group health plans may not request the participant's genetic information that we obtain from this research. However, if the participant chooses to share this information with their medical provider, it may become part of their medical record, meaning that insurance companies could view and access it.
- Health insurance companies and group health plans may not use the participant's genetic information when making decisions regarding their eligibility or premiums
- Employers with 15 or more employees may not use the participant's genetic information that we obtain from this research when making a decision to hire, promote, or fire the participant or when setting the terms of their employment.

However, there are some exceptions to GINA:

- This law does not protect the participant against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.
- GINA does not apply to the following groups. However, these groups have policies in place that provide similar protections against discrimination:
    - Members of the US Military receiving care through Tricare
    - Veterans receiving care through the Veteran's Administration (VA)

- The Indian Health Service
- Federal employees receiving care through the Federal Employees Health Benefits Plans

Brain Protein Results: GINA does not provide protection against discrimination based on the results from the participant's amyloid and tau PET scan. While we will not release these results to any individual or organization without the participant's or LAR/POA's prior request and approval, the participant or LAR/POA may decide that they want the results shared with the participant's medical providers. If the participant or LAR/POA chooses this option, there is the possibility that the participant's doctor may add the information to your medical record, making it accessible by health insurance companies. There is therefore 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 you and the participant 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 not receive any personal benefits from being in this study. However, you may benefit from learning more information about DAT, available indicators of risk for this disorder, and your loved one's personal status on these indicators. For example, you, the participant, and your family may use this information to inform health decisions or plan for the future. If you choose to share this information with your medical providers, they may use it to assist with treatment planning. Additionally, others may benefit from the knowledge gained from 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 you or the participant decide that you are no longer interested in participating in the study, you can halt participation at any time. If you are the LAR/POA for the participant and do not wish to take part or wish to stop participation, the participant will not be eligible to continue. If you are not the LAR/POA but wish to stop participation, the participant may select any person meeting the criteria for study partner listed in Section 3 above to replace you.

If you have already taken part in the DAT risk disclosure session and wish to stop participating, the study team will work with you to ensure that you 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 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.
- 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?

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you or your insurance provider will be billed for all costs of treatment as the study does not provide compensation for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

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?

You will receive $10 for completing the study session, and $10 for completing each of the two follow-up sessions ($30 maximum 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?

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

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, you and the participant will 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. Audio recordings will be recorded using a HIPAA-compliant voice recorder. Video recordings of the Zoom for Health meetings with be recorded as a video file. As soon as you have completed your session, these recordings will be transferred into a secure drive on the University of Michigan Psychiatry server.

If you choose to complete any sessions via video conference, the study team will send you a secure link to sign this form and to join the appointment through your email. All sessions will be completed using University of Michigan BlueJeans or Zoom for Health, two HIPAA-compliant, secure video conferencing systems. We may utilize other virtual HIPAA-compliant platforms approved by the University of Michigan if they become available. 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. As with the in-person visits, we will record your responses during the initial session. These recordings will be stored electronically on a secure drive on the University of Michigan Psychiatry server.

None of the results from your study 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.

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 National Institute on Aging 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.

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
- 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: **Annalise Rahman-Filipiak, Ph.D.**
Mailing Address: Neuropsychology Section, Department of Psychiatry
2101 Commonwealth Blvd., Suite C, Ann Arbor, MI 48105
Telephone: (734) 936-3180

Study Team
Mailing Address: Neuropsychology Section, Department of Psychiatry
2101 Commonwealth Blvd., Suite C, Ann Arbor, MI 48105
Telephone: (734) 764-7402

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?

You will receive a copy of this signed and dated informed consent form. Your signature in the next section means that you have received copies of all of the following documents:

- 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/Assent 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/Assent to audio/video recording solely for purposes of this research
This study involves audio and/or video recording. If you do not agree to be recorded, you CANNOT take part in the study.

_____ Yes, I agree to be audio/video recorded.

_____ No, I do not agree to be audio/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): _____