UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Social Prescribing and Relationship Cognitive Strategies (SPARCS): Pilot Randomized Controlled Trial (IRBMED: HUM00258121)

Company or agency sponsoring the study: National Institute of Mental Health

Names, degrees, and affiliations of the principal investigator and study coordinator:

Principal Investigator: Paul Pfeiffer, MD, Department of Psychiatry, University of Michigan

Study Coordinator: Jennifer Jagusch, MSW, Department of Psychiatry, University of Michigan

1.1 Key Study Information

You are 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.

This study involves a process called randomization. This means that the intervention you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

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 a breach of confidentiality and emotional distress or psychological discomfort. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by gathering knowledge about treating loneliness.

We expect that you will be receiving study interventions and study follow-up for 6 months.

You can decide not to be in this study. Alternatives to joining this study include standard behavioral health care, such as Collaborate Care Management or psychotherapy.

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 in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: We are testing the acceptability and feasibility of two Collaborative Care interventions for improving loneliness:

1. **Social Prescribing** focuses on setting goals and using problem-solving skills to increase social activity.
2. **Brief Cognitive Therapy** focuses on addressing thought patterns about yourself or social situations that act as barriers to social connection.

Research has shown that each of these treatments may help improve loneliness, but they have never been tested together, or in a primary care setting.

For this pilot study, we have adapted these treatments for Collaborative Care, and we are studying whether they are practical and well-received by patients who might use them.

In a future study, we hope to test whether treating loneliness with these interventions is effective for reducing suicide risk.

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?

Patients can take part in this study if they meet the following criteria:

- 18 years or older
- Experiencing loneliness
- Have had thoughts of suicide in the past year

Patients will not be able to take part in this study if they:

- Aren't fluent in English
- Don't have reliable phone access
- Have memory problems that would interfere with treatment
- Are receiving or planning to receive mental health care outside of primary care
- Won't be able to take part in a 6-month study for another reason, such as planned travel or terminal illness

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

We expect to enroll up to 100 participants from two study sites: Michigan Medicine Canton and Brighton Health Centers.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

- First, we will ask for contact information to help us stay in touch with you during this study.
- Second, we will ask you to take a short multiple-choice survey on depression and anxiety symptoms. That survey will take about 10 minutes to complete.
    - If you score positive for depression or anxiety on this survey, we will recommend you delay your study participation for up to 2 months so that you can be assessed and begin treatment for those conditions in Collaborative Care *[not research].* You can decline this option if you prefer.
- Third, we will ask you to take a 45-minute multiple-choice survey that will ask more questions about your life and mental health. You can take this survey online or over the phone.

After this survey, you will be randomly assigned to 1 of 3 treatment arms (assigned by chance in a process similar to "flipping a coin"):

- **Option 1**: You will first receive Social Prescribing, and then switch to Brief Cognitive Therapy.
- **Option 2**: You will first receive Brief Cognitive Therapy, and then switch to Social Prescribing.
- **Option 3**: You will receive an informational booklet on improving loneliness. You may initiate or continue Collaborative Care for other conditions on a *not research* basis.

If you are randomized to Options 1 or 2:

- Both interventions will be delivered by your Behavioral Health Care Manager during your Collaborative Care Management appointments. These appointments typically take place over video call (telehealth).
- If you are not already established with Collaborative Care Management, you will receive a one-time introduction and scheduling call before your first appointment.
- Each intervention consists of 4 sessions, delivered over 3 months. You will also receive a one-time introductory session before starting the first intervention.
- Each "session" takes about 20 minutes. Additional time may be spent during your Collaborative Care Management appointment focusing on your usual care for other conditions and is not part of this research study.
- Between sessions, you will be given "homework" tasks, such as filling out worksheets or completing goals that you set with your provider.
- The Social Prescribing or Brief Cognitive Therapy portion of your appointment *only* will be audio recorded using a voice recorder or secure meeting software. Audio recordings will be reviewed

by study staff for training and compliance purposes. You must agree to be audio-recorded to participate in the study.

Regardless of your treatment arm assignment:

- We will ask you to take 2 more surveys, 3-months and 6-months from your first survey. Those surveys will ask similar questions and will take about 45 minutes to complete. You can take these surveys online or over the phone with a researcher who won't know your treatment arm assignment.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you attend all your scheduled appointments and report any adverse reactions you may have during the study.

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

- The baseline, 3-month, and 6-month surveys will each take about 45 minutes.
- Each study intervention consists of four 20-minute sessions. There is also a one-time 20-minute introductory session. Overall, these sessions will take about 3 hours over 6 months.
    - The study intervention is delivered as part of your Collaborative Care Management appointments. These appointments may also involve usual care that is separate from your study participation. This time estimate does not include appointment time dedicated to usual care.
- The time required for between-session "homework" will vary. In general, you may spend 1-2 hours working on homework tasks in the weeks between sessions.

4.3 When will my participation in the study be over?

Your participation in this study will end once your 6-month survey is complete. The entire study is expected to last 3 years.

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?

The most common (i.e., occurring in 10-25% of patients) risks expected in this study are:

- Tiredness or fatigue from taking study surveys
- Emotional discomfort or distress from survey or (if you are randomized to the study interventions) from intervention session content
- Experiencing thoughts of suicide during your study participation

Less commonly, there is a risk of loss of privacy or confidentiality. This might happen if:

- Infrequently (i.e., occurring for 1-10% of patients), the study team may need to break confidentiality for safety reasons (i.e., if you are at risk of harming yourself or someone else, or

to report child or elder abuse or neglect). Whenever possible, the researchers will notify you before we break confidentiality for these reasons.

- Rarely (i.e., likelihood to occur is less than 1%), a data breach could occur, resulting in unauthorized individuals outside this study discovering that you were a participant in this research or gained access to your identifiable health information. This may result in social or economic harm, such as discrimination by employers or insurance providers.

We take the following steps to minimize these risks:

We expect any tiredness or emotional distress caused by study activities to be temporary. You may take breaks during surveys, refuse to answer any questions that make you uncomfortable, or end your participation in the study at any time.

Research staff are trained to manage emotional distress and suicidal crisis situations. Each survey will ask about recent thoughts of suicide. If you receive the study interventions, your provider may also ask about thoughts of suicide. If you report thoughts of suicide, research staff are trained to assess whether you are at immediate risk. If needed, we may connect you with additional support. That could include:

- Giving you a list of crisis resources
- Having you talk with a study clinician
- Connecting you with the National Suicide Crisis Line
- Making a plan to get you to emergency medical services

If staff are concerned that you might harm yourself and cannot contact you to conduct a complete risk assessment or make a safety plan, we may call your emergency contact(s). If we cannot reach you or your emergency contact(s), we may need to contact police for a welfare check. Research staff may also notify your outpatient treatment provider(s) and/or a study clinician of your thoughts of suicide.

The researchers have adopted privacy and confidentiality procedures to prevent data breaches and protect your health 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.

Keep in mind, as well, that the committee (IRBMED) that reviews this study does not review risks associated with procedures that are conducted as part of your regular medical care and are not part of the research, including those marked "[Not research]" in section 4.1, above. Risks associated with your regular medical treatment should be discussed with your regular doctor.

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 or any other provider or hospital you visit**.**

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 experience any personal benefits from being in this study. It's possible that you may experience an improvement in loneliness and reduction in suicide risk because of the study interventions. Even if you do not personally benefit, future patients 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?

There may be other ways of treating your condition. These may include other programs for improving loneliness or specialty mental health care for suicide prevention. Your doctor can tell you more about these other treatments, their risks and their possible benefits. You should have this discussion about the risks and benefits or other alternatives prior to making your decision about whether you wish to take part in this research study.

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?

Tell us if you are thinking about stopping or decide to stop. It is important to tell us if you are thinking about stopping so any risks can be evaluated by the researchers. We will also tell you how to stop safely and discuss what follow-up care and testing could be most helpful for you. If you decide to leave the study before it is finished, please tell one of the researchers listed in Section 10 "Contact Information" (below).

You are free to end your participation partially or completely in the study. An example of partially ending your participation would be to discontinue receiving study intervention, while still allowing continuation of study follow-up procedures.

Please note that any information collected before you withdraw will be kept and used to complete the research.

Please note that even if you withdraw consent for further follow-up or contacts, if the study doctor becomes aware of additional safety information this will be reported to the sponsor in order to comply with legal or regulatory requirements.

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 researchers believe 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?

The study will pay for research-related items or services that are provided only because you are in the study. The procedures described in section 4.1 may include some non-research procedures. Those designated as "[Not research]" will not be paid for by the study. If you are not sure which procedures or services the study will pay for, ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

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.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By consenting to participate in this study, 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 be given a $25 gift card after completing the baseline survey and a $35 gift card for completing each of the follow-up surveys (3 months and 6 months from now), for a maximum total gift card payment of $95.

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

This research is funded by the National Institute of Mental Health (NIMH). No person or organization has a financial interest in the outcome of the study, and no person or organization will 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.

9. CONFIDENTIALITY OF PARTICIPANT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

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?

Your participation will occur at Michigan Medicine. Your data will be kept confidential, to the extent permitted by applicable laws, in the following manner:

- Your name will not be used in any reports about the study
- You will be identified only by a study code
- Your identifying information will be kept secure

Despite these protections, some study data may contain information that could be used (perhaps in combination with other information) to identify you (e.g., initials, date of birth).

<u>How your data will be stored:</u>

- The survey data we collect from you will <u>not</u> be made a part of your regular medical record. However, if you are randomized to receive the study interventions, your appointments with your Behavioral Health Care Manager will be documented in your medical record.
- Your research information will be stored electronically in encrypted, password-protected computers.
- Your information will also be stored on the cloud; the term “cloud” refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud services used to store files associated with this study meets University of Michigan and HIPAA protection standards. Only members of the study team will have access to your study information.

- No identifiable information about you will be stored with your survey data. Instead, you will be assigned a unique study ID number that will only identify you to study staff.
- Audio recordings of your study intervention sessions will be stored using encryption.

If a data breach occurs,

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, we may share information with appropriate authorities if we think you may harm yourself or others. We may also share your information with other researchers.
- The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at https://www.era.nih.gov/erahelp/CoC_Ext/Content/A-Introduction/Introduction.htm

If you tell us or we learn something that makes us believe that you or others have been or may be abused, neglected, or exploited, we may, and in some cases must, report that information to the appropriate agencies.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. 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.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called

protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers

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 and for quality improvement purposes.
- 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
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular Michigan Medicine medical record.
- If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.
- 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 does not expire, unless you cancel it. 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: Paul Pfeiffer, M.D.
Mailing Address: 2800 Plymouth Rd., NCRC, Building 16, Ann Arbor, MI 48109
Telephone: 734-845-3645

Study Coordinator: Jennifer Jagusch
Mailing Address: 2800 Plymouth Rd., NCRC, Building 16, Ann Arbor, MI 48109
Telephone: 734-222-7437

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
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 be given a copy of this informed consent document.

12. STORAGE, USE, AND SHARING OF INFORMATION COLLECTED OR GENERATED IN THE STUDY DESCRIBED ABOVE

The information that follows applies to information collected and/or used in both the main study as well as to unspecified future use of your information.

12.1 What is meant by the storage, future research use, and sharing of study participants' medical information and leftover samples (sometimes referred to as biospecimens) taken from me?

Individual researchers, the University of Michigan, and companies that design and sponsor studies often want to keep subjects' medical information to use in future research. These future research uses take different basic forms, which are described below. The medical information may also be shared with other researchers so that they can use it in their studies.

The purpose of storing, using, and sharing participants' medical information is to promote more research that might lead to useful medical discoveries.

In some cases, researchers need your consent to store, use, and share your medical information; in other cases, they can store, use and/or share it without your consent. Whether or not researchers need your consent depends on if the stored information would still be identifiable as yours or whether the researchers would first remove all information connecting them back to you.

12.2 Types of storage, future research use, and sharing in this study

For purposes of this research study, your collected private information will be shared with the study sponsor, NIMH, its collaborators, and associated research partners.

With appropriate institutional and regulatory permissions, your collected private information and identifiable biospecimens could be used for future research with other researchers and companies, including those in other countries, with or without your consent.

In addition, after identifiers are removed from your private information, the information could be used for future research studies by U-M and shared with other researchers or companies, including those in other countries, without your additional informed consent.

This study receives funding from the National Institutes of Health (NIH). NIH requires us to develop a plan regarding how we may share some information about you with other researchers so that they can use it in their studies. Their research may be similar to this study or may be completely different. Once we have shared information about you with other researchers, we will not be able to get it back.

Although we will do our best to protect your information, both during storage and when sharing it with others, it's possible that unauthorized people might gain access to your information.

We will remove all details from your information that identify you individually and assign it a random code before sharing it with other researchers. Once we have removed and destroyed those identifying details, it will be impossible for others to know the information came from you.

Researchers who wish to access your information must obtain permission to access your information.

You will not find out the results or directly benefit from future research utilizing your information. Sharing your information may contribute to research that helps others in the future.

You do not have to agree to storage and sharing of your information if you do not wish to. You may take part in this study even if you do not want us to share your information with other researchers. You will indicate your choice regarding storage and sharing of your information verbally to the researcher reviewing this consent document with you.

13. CONSENT

If you agree to take part in this study, please indicate your consent verbally to the study team member reviewing this document with you.

By consenting to take part in this study, you agree that:

- I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with the study team member. 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.

- This study involves audio recording. Agreeing to be audio recorded is a requirement for participating in this study. I agree to be audio recorded solely for the purposes of this research project.