# UNIVERSITY OF MICHIGAN
# CONSENT TO BE PART OF A RESEARCH STUDY

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

**Study title:**
Targeting sleep homeostasis to improve alcohol use disorder treatment outcomes (M-STAR Study)

**Company or agency sponsoring the study:**
National Institute on Alcohol Abuse and Alcoholism (NIAAA)

**Principal Investigator:**
J. Todd Arnedt, Ph.D., Associate Professor, University of Michigan Department of Psychiatry

**Study Coordinator:** Mandilyn Graham, MA, LCPC

### 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.

*What is research?* Research studies hope to make discoveries and learn new information about certain conditions and how to treat them. You should consider the reasons why you might want to join a research study or why it might not be the best decision for you at this time.

Research studies don't always offer direct benefit. 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, such as amount of time required. In your decision to participate in this study, consider all of these matters carefully.

*Purpose:* This research study is looking at two non-drug sleep therapies delivered by telemedicine for insomnia in people who are seeking treatment for alcohol use disorder. We want to test whether these programs can help improve the symptoms of insomnia and associated daytime symptoms. We will collect information about your sleep, daytime symptoms, and drinking habits throughout the study.

*Randomization:* This study uses randomization to assign people to the different therapy programs. This means that the therapy program you receive is assigned by chance, like flipping a coin.

*Risks & Benefits:* 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 feelings of sleepiness and other symptoms associated with insomnia, discomfort associated with answering

sensitive questions, and the potential loss of confidentiality. More detailed information will be provided later in this document.

You might experience some benefit in the way of improvements in your insomnia, and future patients might benefit from new and improved ways of managing their insomnia. More information will be provided later in this document.

*Expected commitment:* We expect that most people will complete their study participation in about 1.5 years. This includes a baseline period, 6-weeks of therapy, and 1 full year of follow-up every few months after you finish therapy.

You can decide not to be in this study. If you are looking for alternatives to managing your insomnia, speak to your health care provider or alcohol use disorder therapist.

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:**

Insomnia is common in people who are in treatment for alcohol use disorder. It can impact both sleep quality and daytime functioning, as well as make it harder to treat the underlying substance abuse. This study is looking at two types of therapy to help manage insomnia specifically for people also in treatment for alcohol use disorder.

## 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?**

You can be in this study if you are between the ages of 18-65 years *and* intend to enroll in a University of Michigan Addiction Treatment Services (UMATS) treatment program or comparable treatment program for alcohol use disorder *and* have insomnia. It's also important that you have a stable housing arrangement to take part in the sleep therapies and access to a Wi-Fi capable device and Wi-Fi network for delivery of therapy. You cannot be in this study if you have a sleep disorder other than insomnia (like sleep apnea), or have other complicated medical conditions.

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

We expect 150 people to take part in this study.

## 4. INFORMATION ABOUT STUDY PARTICIPATION

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

If you decide to be in this study, you will be asked to do the following:

1. Complete a series of surveys and interviews. Some of these may have already been completed; additional assessments will be completed remotely via the internet.
2. Receive and wear a daily wrist-worn sleep tracker, called an ActiWatch, and keep a sleep log for the next 7-14 days
    a. ActiWatch should not be worn in water
    b. May be removed for showering and/or bathing
3. Complete 3 total nights of sleep testing, either in lab (polysomnography or PSG) or home sleep testing. Sleep testing consists of 2 nights at baseline and 1 night following completion of therapy sessions
4. Participate in 6 remote therapy sessions via video chat over about 6 weeks; these sessions will be audio recorded with your permission. Audio recording is not required for participation in this study.
5. Complete follow up surveys at 4 different times - 1 week, 3 months, 6 months, and 12 months- after completing therapy sessions
6. Receive and continuously wear an ActiWatch and keep a sleep log for 1 week each at 4 different times - 1 week, 3 months, 6 months, and 12 months after completing therapy sessions

If you decide to be in this research study, you will be randomly assigned to one of two therapy groups that focus on insomnia. People in both groups receive one-on-one remote therapy sessions delivered by

video chat. The study therapist will video chat with you once a week for 6 weeks to talk about your sleep. You will talk to the therapist via BlueJeans video chat platform. These sessions will last between 30-60 minutes, and will be audio-recorded with your permission. We record all of the sessions to make sure that the therapist is conducting the sessions the same way for everyone. These recordings will be used only for this research study.

You will complete up to 3 nights total of sleep testing (PSG) either in the Sleep Lab or home environment (1-2 nights at baseline and 1 night after completing therapy). A PSG is a test that gives us information about your sleep including things like: sleep stages, snoring, muscle tone, body position and movements, blood oxygen levels, and breathing events. You will have sensors connected to your head and body. If your studies are in the sleep lab, a research technician will monitor your sleep from another room and will wake you each morning to remove the sensors. Home sleep tests provide us with the same information we would obtain in the lab, however they allow you to complete the testing at home. If you complete your sleep testing at home, you will be provided all materials necessary to return the device to the study team. If you are determined to have another sleep disorder (for example, Sleep Apnea) following your first night of PSG, your participation in the study will end and you will be referred to the Michigan Medicine Sleep Disorders Center for clinical follow up.

**4.2 How much of my time will be needed to take part in this study?**
The initial visit, online or in-person, will take about 1-2 hours to complete, and each of the 4 post-therapy visits will take about half that time (30-minutes to 1 hour). The overnight sleep tests involve your regular sleeping hours, plus some time to get you set up. The 6 therapy sessions last 30-60 minutes each and will occur weekly.

**4.3 When will my participation in the study be over?**
Your total time in the study will be about 1.5 years. This includes the 2-week baseline period, 6 weeks of therapy, and a year of follow-up after your therapy is over. The entire study is expected to last about 5 years.

**4.4 What will happen with my information used in this study?**
Your collected research information may be shared with the National Institutes of Health, the funder of this study.

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

Your identifiable private information 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?**
Some of the questions that will be asked are about sensitive or personal information. These questions may make you feel uncomfortable or anxious. You may skip any question you don't want to answer and you are free to leave the study at any time. The sleep tracker (ActiWatch) is worn on the wrist like a regular

wrist watch. It may cause discomfort and/or skin irritation. If you experience discomfort or irritation you may remove the sleep tracker. The sensors associated with the overnight sleep tests might cause similar discomfort or skin irritation. These risks are usually short-lived and go away once the sensors are removed and sites cleaned.

In studies for insomnia and insomnia therapies, feeling deprived of sleep is a risk. This can make you sleepy, tired, and irritable or mentally foggy. These feelings tend to go away or become less bothersome over time. We try to minimize the amount of sleep deprivation you experience through the therapy and will monitor you throughout the treatment period.

Additionally, there may be a risk of loss to confidentiality or privacy. 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?**
We have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when we are careful to avoid them. Please tell us (see Section 10) about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors or your UMATS therapist**.**

**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?**
The therapies offered in this study represent enhanced levels of care for people with alcohol use disorder. As such, you might benefit from these; however, there is also a chance that you may not receive any personal benefits from being in this study. By being in this study, you will contribute to our knowledge and understanding of alcohol use disorder and insomnia, which may help individuals like you in the future.

**5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?**
Yes, we will tell you if we 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 you decide not to take part in this study you may continue with your normal UMATS therapy and other treatments. Being in this study it voluntary, and there is no penalty to you for not participating.

## 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 us 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 email the study coordinator, Mandilyn Graham (mstarstudy@med.umich.edu), or call one of the people 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?**
We do not expect that you would experience any harm if you decide to leave the study before it is finished.

**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 we may need to end your participation in the study. Some examples are:

- We 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 study instructions
- 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. Because the therapy sessions are done via video chat you may be charged for data used on your data plan bill should you not be connected to Wi-Fi.

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 are eligible for up to $605 for completing the entire study. Payment is given out based on which pieces of the study you complete:

**Prescreen**

- **$5 total possible for completion of online prescreen survey**

**Baseline**

- Baseline - $175 total possible, to be sent after all measures are complete and devices (ActiWatch and Prodigy Sleep System) are returned
  - $25 for completing in-person assessments or remote screening assessments
  - $25 for remotely completing web-based measures
  - $25 for completion of actigraphy period and return of device
  - $50 per night of PSG or HST for a total possible $100

**Post-treatment**

- $50 for completing questionnaires and assessments
- $25 for completing 1-week of at-home sleep monitoring with the ActiWatch
- $50 for 1 night of PSG or HST

**Follow-up assessments at 3-months, 6-months and 12-months post-treatment**

- $5 apiece ($15 total possible) for contacting us to schedule each of your follow-up appointments
- $50 for each time you complete questionnaires and assessments ($150 possible)
- $25 for completing 1-week of at home sleep monitoring with the ActiWatch ($75 possible)
- $20 apiece ($60 total possible) for referrals of minimally eligible individuals

**8.3 Who could profit or financially benefit from the study results?**
It is unlikely that anyone involved with this study will financially benefit from the 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 SUBJECT 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?**
**Research Information:** To keep your information confidential, we'll create a unique study ID number to use for your information, rather than your name or any other details that someone could use to identify you. Although we'll keep a list of all the people who participate in the study, no one outside our study team will be able to figure out who participated or which people gave which answers. Your name and other identifying information will be kept securely and separately from your research data.

**Therapy sessions:** The therapy sessions will be delivered remotely via BlueJeans or Zoom Healthvideo conferencing (https://www.bluejeans.com/ or umich.zoom.us). BlueJeans and Zoom Health provide cloud-based audio/video/content-sharing conferencing services. U-M's agreement with BlueJeans and Zoom Health includes a Business Associate Agreement. This means individuals may use this service to share Protected Health Information (PHI) regulated by HIPAA. For more information, BlueJeans Security and Privacy agreements with the University of Michigan can be found at https://safecomputing.umich.edu/dataguide/?q=node/181. Zoom Health Security and Privacy agreements with the University of Michigan can be found at https://safecomputing.umich.edu/dataguide/?q=node/249 . Your confidentiality will be kept to the degree permitted by the technology being used. Although every reasonable effort has been taken, confidentiality during actual web-based or phone communication procedures cannot be guaranteed.

**Certificate of Confidentiality:** This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate we may not disclose or use information, documents, or recordings 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 recordings 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 NIAAA 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 if we learn of information about suspected or known sexual, physical, or other abuse of a child or older person, or threats of violence to self or others. If this comes up, we will need to notify the authorities for safety reasons, but we would only share the minimum amount of information required by law.

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:** This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

**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:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)

- 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
- Demographic information
- Personal identifiers

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

- We may need the information to make sure you are eligible to take part in the study.
- We may need the information to check your test results or look for side effects.
- University, government officials (e.g. study sponsors, NIAAA), 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 (the NIAAA) or safety committees may need the information to make sure the study is done safely and properly or to analyze the results of the study
- We 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 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?**

**We will save and continue to use your collected information about you for future studies and analyses**. 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).

**Additionally, your study data will be submitted to the NIAAA-Data Archive ($NIAAA_{DA}$) at the NIH.** The $NIAAA_{DA}$ is a large database where de-identified study data from many NIAAA studies is stored and managed. De-identified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your data helps researchers learn new and important things about alcohol problems more quickly than before. Other researchers across the world can then request your de-identified study data for other research. Every researcher (and institutions to which they belong) who requests your de-identified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with $NIAAA_{DA}$. The study data provided to $NIAAA_{DA}$ may help researchers around the world learn more about alcohol problems and how to help others who have problems with alcohol. NIAAA will also report to Congress and on its website about the different studies using $NIAAA_{DA}$ data. You will not be contacted directly about the study data you contributed to $NIAAA_{DA}$.

You may decide now or later that you do not want your study data to be added to the $NIAAA_{DA}$. You can still participate in this research study even if you decide that you do not want your data to be added to the $NIAAA_{DA}$. If you know now that you do not want your data in the $NIAAA_{DA}$, please tell us before leaving the clinic today. If you decide any time after today that you do not want your data to be added to the $NIAAA_{DA}$, call or email us, and we will tell $NIAAA_{DA}$ to stop sharing your study data. Once your data is part of the $NIAAA_{DA}$, we cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about $NIAAA_{DA}$, this is available on-line at https://nda.nih.gov/niaaa.

**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 contacting any of the people 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: J. Todd Arnedt, PhD
Mailing Address: Sleep and Circadian Research Laboratory
Department of Psychiatry
4250 Plymouth Rd, Ann Arbor, MI 48109
Telephone: 734.764.1470

Study Coordinator: Mandilyn Graham, MA, LCPC
Mailing Address: Sleep and Circadian Research Laboratory
Department of Psychiatry
4250 Plymouth Rd, Ann Arbor, MI 48109
Telephone: 734.232.0276

**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 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

**Sig-A**

**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): _____

**Sig-B**

**Consent to audio recording solely for purposes of this research**

This study involves audio recording for the purposes of ensuring that the treatment is delivered properly. If you do not agree to be recorded, you may still take part in the study.

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

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

Print Legal Name: _____

Signature: _____

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

## CONSENT TO SAVE RESEARCH INFORMATION FOR FUTURE STUDIES

We would also like your permission to keep some of your identifiable information collected in the main study, so that we may study it in future research.

You can take part in the main study even if you decide not to let us keep your identifiable information for future research. If you give us your permission, we will use this information for future research studies that are either related to the main study or are separate research questions. Even if you give us permission now, you can change your mind later. Keep in mind, however, that once we have used your information in a study, we may not be able to un-use it.

We may share your research information with other investigators, 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 information, we will not be able to get it back.

Future use of your identifiable data will be conducted in compliance with applicable regulatory requirements. There is a risk of confidentiality breach; we will follow the same data protection practices listed in Section 9 of this document to keep your information safe. Allowing us to do future research with your information will not benefit you directly. With appropriate permissions, your information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information 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.

**Sig-D**

**Consent to Collect for Unspecified Future Research**

This project involves the option to allow the study team to keep your identifiable research data for use in future research. I understand that it is my choice whether or not to allow future use of my data. 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.

_____ Yes, I agree to let the study team keep my research data for future research.

_____ No, I do not agree to let the study team keep my research data for future research.

Print Legal Name: _____

Signature: _____

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

**Sig-G**

**Principal Investigator or Designee**

I have provided this participant with information about this study that I believe to be accurate and complete. The participant indicated that they understand the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

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