Computerized Game-based Vestibular Rehabilitation: Assessment of Feasibility and Motor Learning

NCT03589859

September 26, 2022

Participant Name: **Date:**

Title of Study: An Assessment of Open Access Audio of the Clinical Encounter on Veterans and their Care

Principal Investigator: Saul J. Weiner, MD

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether or not to volunteer for a research study being funded by the Department of Veterans Affairs, Health Services Research and Development about whether giving patients an audio recording of their medical visit that they can easily access from any device connected to the internet, and share with others if they wish, is helpful to them and leads to better health care outcomes. This initial information is to give you key information to help you decide whether to participate. We have included detailed information after this information. Ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to determine whether audio recording visits for patients is helpful to them and leads to better outcomes. If you decide to participate in this study you will be handed a small audio recorder to bring into your visit and return when you leave. The audio recording will be transferred to a computer server that is highly secure. You may then be emailed a link that allows you to access the recording and listen to it whenever you want. If you receive the link you can share it with others if you wish to.

Because this is a research study in which we are trying to determine if these audio recordings are helpful, we are carrying it out like a randomized trial, meaning that you may not actually get access to the audio recording. This is similar to research studies of new drugs in which some patients get a placebo. By giving some patients access to the audio and others no access, we can compare the two situations and see if the audio recording is beneficial.

In this study we are testing two ideas about how audio recordings may be helpful: One is that the recording will help you better understand your treatment plan and that, as a result, you will have better health outcomes. The other is that your health care provider may do a better job of explaining information and communicating with you during the visit when they know the visit is being recorded. We plan to test these ideas by seeing if participating in this study leads to improvements in patient's medical conditions, whether it's lowering of high blood pressure or better control of diabetes, for instance, and whether it reduces the number of emergency department visits and hospitalizations. We'll also see if patients who participate are more likely to refill their medications on time and make it to all appointments. Finally, we plan to call some of the patients who participate a couple of weeks after their visit to see if the audio recording has been helpful to them.

In order to know whether audio recording influences how your provider communicates with you, we need some recordings in which they are unaware they are being recorded at the time of the visit. As a result we may ask you not to show the recorder to your provider. Your provider has already agreed to this plan.

By doing this study, we hope to learn whether bringing this audio recording technology into the VA will benefit Veterans. Your participation in this research will last about six months, meaning that during that time a research data analyst will collect data mentioned above (e.g. on your blood pressure, diabetes status if you have it, medical refills, and appointments). Also, for about 20% of the visits, a research assistant will look for specific information in your medical that might indicate you are having difficulty managing your care (such as missed appointments or not refilling medications) and listen to the audio to see if your physician is attempting to assist you. You will also be asked to complete a brief questionnaire at the start of the visit and may receive a follow up call as described below. You may complete a brief exit survey.

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WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There are two reasons you may choose to participate in this study. The first is that there is a 45% chance (slightly less than half) that you will have access to the audio after the visit, meaning you will get a link to it in your email that you can use to listen to the visit and share it with others if you wish. This may be helpful to you. The other reason is you may feel like you'd like to help the VA determine if this technology is beneficial to Veterans even knowing that you may not get access to the audio yourself.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

For a complete description of risks, refer to the Detailed Consent below.

There are also a couple of reasons you may prefer not to participate. The first is that carrying an audio recorder into your visit may seem like a hassle that you do not want to deal with today so you'd prefer not to get involved. The other is that you are personally not comfortable with the fact that someone on the VA research team conducting this study may listen to the audio recording, even if it's for research purposes.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Saul Weiner of the Jesse Brown VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: saul.weiner@va.gov or call him at 312-519-2697.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

As noted above, this research is being done to find out if giving patients audio recordings of their visits is helpful to them both in terms of understanding their health care and knowing what to do to care for themselves when they get home. We also would like to find out if health care providers, such as physicians and nurse practitioners, communicate more effectively when they know the visit is being recorded for you. If the audio recording is, in fact, helpful either to you or to how your provider communicates with you it may even lead to better health care outcomes, so we will be studying those too.

With this research we hope to learn if audio recording visits and giving patients access to those audio recordings improves your ability to follow your care plan and improve your health.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 1,731 people will participate in this research study at Jesse Brown VAMC.

Additionally, about 577 people will participate at Louis Stokes Cleveland VA Medical Center for a total enrollment of 2308 people at all sites.

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HOW LONG WILL I BE IN THE STUDY?

Your direct involvement in the study occurs at today's visit and, in addition, there is a 40% chance (slightly less than half) that we'll follow up with a 3-5 minute phone call in 1-2 weeks time. Also, if you receive access to an audio recording of your visit you will be able to listen to it for six months. Our research team will follow up on data related to your visit and on your use of the audio recorder, if you receive one, for 6 months.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you choose to participate in the study, here is what will happen:

1. After you sign the consent form, you will be asked to complete a short questionnaire that measures how familiar you are with some medical words and takes about 1 minute.

2. You will be handed a small audio recorder to turn on just before your visit. We will tell you whether to keep it out in the open or hide somewhere, such as in a jacket pocket.

3. When you leave your appointment we will collect the audio recorder from you. We may also ask you to complete a brief questionnaire asking you about whether you found the experience valuable, how much effort it took, and whether you were comfortable participating. There is about a 25% chance you will be asked to do this questionnaire. We will then tell you whether you are in the group that will get access to the audio recording or the control that will not get access. If you get access, your provider will as well.

4. If you are in the group that gets access, after your visit, the research assistant will create an account for you in HealthPAL website(https://va.audiohealthpal.com) using your email address and will ask you to create a log-in password. You will receive an email with a link to the audio recording by tomorrow. You can then click on the link which will take you to a web page where you can log in by using your email address as the username and already created password. You will be able to listen to the audio. You will also have the option of securely forwarding it to others if you wish to do so. If you do not access the audio within 7 days after your appointment, we will make an attempt to reach you by phone to see if you are having technical difficulties that we can help resolve.

5. About 1-2 weeks after your visit you may receive a phone call from a research assistant. The chance they will call you is 40%, or a bit less than half. If they call, it will be to ask you some questions about how comfortable and confident you have been following any instructions related to managing your health and healthcare.

That is the end of any activities related to your role in the research. You will have access to the audio recording, if you received the link, for six months following the visit. Meanwhile, the research team will be conducting some analysis of data related to your visit and your use of the audio recording. Pooling your data with that of all other patients who participate they will look at the following: how often you listen to the audio recording and whether you listened to all or just a part of it; whether you refill your medications on time and keep appointments; the results of any questionnaires you completed; your diabetes and blood pressure control, if you have either diabetes or hypertension; and whether you have any emergency department or hospital

admission and, if so, how many. Finally, a research assistant may (20% chance) listen to and analyze the audio recording of your visit to measure whether your doctor interacted with you differently if they knew or didn't know the visit was being recorded for you. As noted above, they will also access your medical record to look for clues you have having difficulty managing your care, so they can listen as to whether your provider is attempting to assist you.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

If you choose to participate in this study, here is what you can expect, and what we ask of you:

1. In addition to discussing this consent form, you will spend about 1 minute before today's visit completing a brief questionnaire in which you will be asked if you recognize some medical terms. This is to measure your approximate level of understanding of medical language. You will also be asked for your email address and how you access the internet, information we may need. In addition the research assistant will show you how turn on and off the audio recorder and where to keep it during your visit. You will be instructed either to have the recorder out in the open or to keep it hidden, such as in your pocket. Finally the research assistant will ask if you have any other questions.

Note: Because of the COVID-19 pandemic, until it is safe to do so, all of the activities above will occur during a phone call with the research assistant, except the completion of the 1 minute questionnaire, your signing this consent form, and the exchange of the audio recorder. These activities will occur while maintaining a social distance of at least 6 feet and with both you and the research assistant wearing masks.

2. During the visit there is nothing you need to do with the audio recorder unless you decide you've changed your mind about participating in which case you can turn it off. You can do this even if your were asked to conceal the recorder. Your physician agreed to be in the study whether you are showing or concealing the recorder and will not be upset if you show that you have it and want to turn it off.

3. When you leave the appointment and exit into the waiting room, the research assistant will be there to collect the audio recorder and to let you know whether you are in the group that will have access to their audio recording. You may also be asked to complete a brief exit questionnaire. The chance that you will receive access to the recording is 45% (slightly less than half). This is decided by a computer and is random. The research assistant will look on the computer after the visit to see which group you are in. If you are in this group the research assistant will request your email address to create your account in HealthPAL

4. You will receive a $20 gift card from the research assistant when you leave. This is to compensate you for the effort and time you have invested in helping with this study.

5. After you leave to go home the audio recording is transferred electronically to a VA computer server that is as secure as the one used to store your medical record. If you are in the group that is going to be able to listen to the recording, the project manager will trim the audio to remove all the identifiers using the audacity software and upload the deidentified audio directly to the HealthPAL website(https://va.audiohealthpal.com) managed by the Geisel School of Medicine at Dartmouth in New Hampshire. This research group is outside of the VA. At this

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point an automated script sends the link to the email address you provide within 24 hours of your appointment.

6. Once you receive the link to your audio, you can click on it using your phone, a computer at home, or any computer with access to the internet. It will take you to a webpage where you'll log-in to your account using the password that was created at the time of your visit. Once you enter that password you'll have immediate access to the audio file. You can also share that link with anyone you wish by emailing it to them. You may repeatedly listen to and/or share the audio at any time over the next six months. The link will then become inactive. If you have any questions or concerns about the audio or how to access it, you can either email or call Gunjan Sharma Gunjan.Sharma2@va.gov or 630-310-4850.

7. About 1-2 weeks after your visit today you may receive a phone call from the research assistant you have just met or another research assistant to ask you some questions about how well you are understanding and managing your own medical conditions. You are free to skip over any questions you do not wish to answer. The chances you'll get a call are 40% (just less than half). The chance of getting a call is random and decided by a computer. You are just as likely to get the call if you have access to the audio as if you do not. The call will take about 5 minutes.

This study is being overseen by a VA research team led by Dr. Saul J. Weiner, MD. At any time you have questions or concerns you are encouraged to reach out to the project manager, Gunjan Sharma. The contact information is the same as provided in item 6 directly above.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

The decision to participate in this study includes some possible risks or discomforts that include the following:

- The decision to carry an audio recorder into your visit, either out in the open or concealed, could be a distraction or inconvenience. It could also make you uncomfortable if you decided to disclose private information that you don't want recorded. We minimize these risks by assuring you that if you are always welcome to turn off the audio recorder during the visit if you decide you don't want to participate for any reason. We also minimize these risks by informing you that your audio recording is managed and stored with a comparable level of data protection and security as your medical record.
- There is the possibility that there could be a breach in confidentiality due to a data security failure related to the storage or transmission of your audio file. As noted, your audio data will be directly uploaded to a server at a medical school where a research team specializes on managing patient audio recorded data. The VA cannot vouch for the security of the system nor take responsibility for any breaches. The reason we are working with this group is that they have developed the technology, which is currently not available within the VA. They have minimized the risk to loss of confidentiality by using the best available software systems and data security protocols which are the same or comparable to VA systems. While we cannot say how likely a data breach is, we estimate the risk to be small.

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- The audio recordings of your visits may be listened to by one or more research assistants who are analyzing how the doctor communicates with you. They will also briefly access your medical record as described above. This will occur to a random sample of 20% of audio recorded visits. If you are in that group, the research team will minimize risk of breach of your confidentiality by removing your name from the data related to you and your care and replacing it with a code. A separate file with your name linked with that code will be stored separately, all on VA approved highly secure server.
- A VA data analyst will look up information already in a national VA database (and based on your medical conditions), about your blood pressure, blood sugar, emergency department and hospitalization usage, prescription refill rates and appointment attendance, but will not have access to your medical record. Again, the risk to your privacy will be minimized by keeping your name separate using the same procedure described directly above.
- The audio recording process could possibly undermine your relationship with your doctor. We have minimized this possibility by only including physicians and other health care providers who want to participate and have consented to participate.
- Questionnaires: As explained above there are three brief questionnaires you will or may be asked to complete: the brief assessment of your knowledge and comfort with medical terminology, a brief survey just as you exit your visit and return the audio recorder, and the one conducted by phone 1-2 weeks from your visit that is intended to find out how confident and comfortable you are managing you're your health needs and care plan. On all three questionnaires we substitute a study identification code in place of your name, so that if anyone were to find the data they would not know that it is about you. We'll keep the study ID code sheet that contains the names of all study participants with their study IDs, in a separate secure location on a server that also belongs to the VA. That sheet will be deleted at the end of the study. There may be some risk in sharing slightly personal data, including how knowledgeable you are about medical terms, and how comfortable you are managing your own care. You may find sharing this information personally uncomfortable. We minimize this risk by assuring you that if, for any reason, you wish not to answer specific questions you need not do so.

There is always a chance that any research process can harm you. In addition to the risks described above, there may be others of which we are not yet aware.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

The study team has explained that by signing this Informed Consent Document, you voluntarily authorize voice a recording to be made while you are participating in this study.

You also authorize disclosure of voice recording to *Geisel School of Medicine at Dartmouth.* The said voice recording is intended for the purposes outlined above: (a) to study whether giving you access to an audio recording of your visit is helpful to you and improves your ability to manage your care; and (b) to see if it improves your provider's communication style.

If you decline to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease participating in this recording program, and may rescind your consent at any time.

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WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

The primary benefits of this study is what we will learn about giving patients access to audio recording of their visits. We do not know if you will personally get any benefits from taking part in this research study. There is a chance, slightly less than half, that you will obtain access to an audio recording of your visit, which you can share with others if you wish. It's possible that this resource will be helpful to you in various ways by enabling you to relisten to parts or all of your visit.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If you choose not to participate your medical visit will be no different than usual or expected.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

As explained above, there are several steps we are taking to protect your privacy. They include:

1. The audio recorder is encrypted using VA approved software that assures that no one unauthorized could listen to anything you record.

2. The audio file will be uploaded and stored on a VA approved server that has the same high level of security as is used to store other patient information. It will be shared with members of our research team who are based at the Hines VA Medical Center. It will be protected by storing it on a secure VA server that is encrypted and intended for securely storing patient information.

3. Your name on all documents and audio files will be replaced with a code. That code will be stored with your name in a separate equally protected VA server folder.

4. If you are the group that is receiving access to the audio recording, a copy of the audio file will be uploaded to the HealthPAL website which is managed by the Geisel School of Medicine team that specializes in managing patient audio files electronically using a secure system that is widely used to protect patient and financial data. They will also receive your email address, which will be linked to the audio file so they know the recording is of the visit with you.

5. If you are in the group that receives the link via email, there will be one addition step to access it: You'll have to login using your password only you know that was created by you after your visit which will then give you access to your audio. If you decide to share the audio with someone else, you'll have to enter both their email address and cell phone number on the web page where you access your audio. They'll receive a text with a 6-digit code that they enter into the link they receive via email, enabling them to set up their own secure password to use to access the audio.

6. The audio will be "streamed" only meaning that you or anyone you share it with can listen to it by clicking on a link but they cannot directly access or transfer the audio file itself.

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At the end of the study, we'll delete the only file that contains your name and the name of other subjects. We may produce written transcripts of the audio recordings but these will not contain your name or any identifiers that could be linked to you. The audio recordings and other data will be archived by the VA for 6 years per VA policy.

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. The study identifier number is: NCT04452331.

Health Information Portability and Accountability Act (HIPAA)

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):
There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule. Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

The research team working on the study will collect information about you. Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as
Your individually identifiable health information used for this VA study includes the information marked below:

☒ Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings
☐ Specific information concerning:
  ☐ alcohol abuse ☐ drug abuse ☐ sickle cell anemia ☐ HIV
☒ Demographic Information such as name, age, race
☐ Billing or Financial Records
☒ Photographs, Digital Images, Video, or Audio Recordings
☒ Questionnaire, Survey, and/or Subject Diary
☐ Other as described:

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

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Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may have access to your information in the performance of their VA/VHA job duties

Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. As noted above, it will be shared with members of our research team who are base at the Hines VA Medical Center. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information. Your information, specifically the audio recording you make of your visit and your email address may be disclosed to: The Geisel School of Medicine at Dartmouth, Department of Biomedical Data Science, in Hanover New Hampshire for the purpose of sharing the audio file with you utilizing software they have developed for this purpose.

Access to your Individually Identifiable Health Information created or obtained in the course of this research: While this study is being conducted, you may or may not have access to the audio recording of your visit, depending on whether you are in the group randomly assigned to get access to the audio, or to the control group which does not. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Revocation: You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator for this study at the following address: saul.weiner@va.gov

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator. The research team will not collect information about you after you revoke the authorization.

If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.

Expiration: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will Expire at the end of this research study.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I RECEIVE A PAYMENT FOR PARTICIPATING IN THIS STUDY?

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You will receive $20 gift card from the research assistant for participating in this study to compensate you for time and effort involved in completing the surveys, which may include a phone call.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

Every reasonable effort to prevent any possible injury from this study will be taken. In the event the study results in any physical, mental or emotional injuries to you, VA will provide necessary medical treatment (not just emergency care) at no cost to you. This does not apply to treatment for injuries that result from if you do not follow the study procedures.

Additional compensation, beyond paying for treatment, has not been set aside. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA District Counsel at (708) 202-2216. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

If you believe that you may have suffered a research related injury (physical, mental or emotional injury or injury caused by loss of confidentiality or privacy), contact:

DURING THE DAY:

Dr. Saul Weiner MD at saul.weiner@va.gov or 312-519-2697 and

AFTER HOURS:

Dr. Gunjan Sharma at 630-310-4850._____

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled.

If you are a VA employee or a student, refusal to take part in the study will in no way influence your employment, subsequent recommendations, or academic progress as applicable. If you do participate, you may discontinue taking part at any time without any penalty or loss of benefits.

For data already collected prior to your withdrawal, the research team may continue to review the data but will not collect further data related to you or your care.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

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You may contact Dr. Gunjan Sharma at 630-310-4850 or Dr. Saul Weiner at 312-519-2697 with any concerns or complaints as to this research study.

If you want to talk to someone who is not involved in this research about your rights as a JBVAMC patient you should contact the Patient Advocate Office at the Jesse Brown VA Medical Center at (312) 569-7959.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Jesse Brown VAMC Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Jesse Brown VAMC IRB at 312-569-6166 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

One of the research study personnel has explained the study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date