

UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Reversing Synchronized Brain Circuits with Targeted Auditory-Somatosensory Stimulation to Treat Phantom Percepts- Stage 2

Company or agency sponsoring the study: The National Institutes of Health: National Institute of Mental Health (NIMH)

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Susan Shore, PhD, Department of Otolaryngology, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, 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 friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this study is to develop and test a subject operated device to lessen tinnitus (ringing in the ear), based on subject-feedback for stimulus presentation. The device being used in the study is not approved by the Food and Drug Administration and is considered to be investigational.

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?

Inclusion and Exclusion Criteria

1. Must be 18 years of age or older.
2. A score of >17 points on the Tinnitus Functional Index, as measured at the screening visit.
3. Must report constant, subjective, preferably unilateral tinnitus without any active external or middle ear pathology.
4. No greater than a moderate hearing loss at the tinnitus frequencies (≤ 55 dB HL) and no greater than a moderate hearing loss (≤ 50 dB HL) from 125 – 6000 Hz.
5. Must be able to modulate their tinnitus with a somatic maneuver

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6. Preferably onset of tinnitus less than one year ago, but present for at least 6 months. Tinnitus should be bothersome.
7. Absence of retrocochlear pathology/ VIIIth nerve lesion
8. No participation in a tinnitus treatment regimen within the past six months or participation in the UM stage 1 clinical trial.
9. Resides within 100 miles of the study site.

Exclusion:

1. Anyone not meeting the above inclusion criteria, and in addition:
2. Diagnosis of Meniere's disease
3. Diagnosis of Semicircular Canal Dehiscence
4. Unilateral or bilateral cochlear implant recipients
5. Diagnosis of acoustic neuroma
6. Reports their tinnitus is pulsating
7. Evidence of retrocochlear disease
8. Patients with any indwelling electronic stimulation devices
9. Current or previous use of any acoustic hearing aid or over the counter personal sound amplification product (PSAP) in the last 6 months
10. Current or former use of any of the following medications within the past 6 months: high dose aspirin (>325mg/day), high dose NSAIDs (ibuprofen, Motrin, Celebrex) (>800mg/day), narcotics (any opioids), lithium, clonazepam, oxazepam, cholinergic medications (anti-dementia medications), anti-depressant medications (serotonin specific reuptake inhibitors; SSRIs, tri-cyclic anti-depressants; TCAs); anti-seizure/convulsant medications (Depakote), anti-psychotic medications (Haldol, Seroquel), Ototoxic medications, other chemotherapy agents, central nervous system stimulants, and benzodiazepines.
11. Current diagnoses of any of the following: obsessive compulsive disorder (OCD), schizophrenia, bipolar disorder, extreme generalized anxiety disorder, drug/alcohol dependence.
12. Pregnant or nursing.

Participant's eligibility will be assessed at an initial examination conducted by an otologist and audiologist consisting of otoscopy, audiometry, tinnitus modulation checklist, case history questionnaire, and the Tinnitus Functional Index (TFI) questionnaire.

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

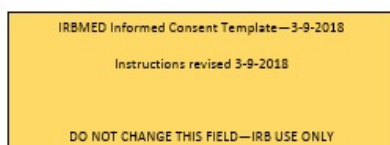
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4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

The following tests will be done:

1. Standard inclusion measures:



- a) Audiometry (measures your range of hearing) and otoscopy (examination of ear canal) will be conducted by a study team member in a sound-proof booth on the second floor of the Kresge Hearing Research Institute.
 - i. These tests are to determine eligibility to participate in the research study and not for diagnostic purposes.
 - b) A case medical evaluation and history survey will be administered by a study team member.
 - i. If mental health issues are identified during the screening process, the screening physician will refer you back to your primary care physician for further evaluation and/or follow-up.
 - c) You will also be asked to perform a series of small physical maneuvers (for example, turn your head to the right) to see how you are able to change your tinnitus.
 - d) A urine pregnancy test will be performed for screening.
2. Outcome measures:
- a) You will complete questionnaires about your tinnitus
 - b) You will perform a tinnitus matching test in which you use a computer program and will be asked to compare the pitch and loudness of your tinnitus to some sounds that are played to you while in the sound booth.
 - c) You will perform a tinnitus masking test in which you will be asked to adjust a sound on the computer in order to find the volume that “masks” your tinnitus.
 - d) These outcome measures will be reassessed on a regular basis, both before, during, and after your use of the device. A personalized schedule of visits will be provided to you at the end of your initial qualifying assessment. The repeated testing before you start with the device allows us to better establish a baseline for your tinnitus.
3. Device: During the research visits, you will be treated with a take home device. During treatment with the device you wear an earphone and two pads. The pads will be placed on your cheek, chin, or neck. When using the device, you will hear different tones of varying volumes from the ear phone and you may or may not feel the stimulation from the pads (this varies person to person). If you do feel something from the pads, it is usually a light tingling or pulling sensation. The settings for both are determined based on your individual hearing and tinnitus profile, and will be adjusted to maintain your comfort. The position of the pads will be determined by the manner in which you can modulate your tinnitus. This is an experimental device that has been developed specifically for this research and we are testing to see how effective it is as a therapy for tinnitus.
- a) To help us fully evaluate the effectiveness of the device, you will be randomized into one of two groups. Two groups will use different device setting, at different periods of time, over the course of the study. Some of these settings will be at levels we expect to be helpful and some of the settings we expect to be unhelpful. Regardless

of the group to which you are assigned, you will be required to not use the device for a period of time at two separate time points during the course of the study. This interval referred to as a “washout period” and is required to help determine the effectiveness of the treatment. To minimize the risk of expectations impacting your results, you and the study team will be blinded to when you are receiving the potentially helpful versus the unhelpful settings. Your tinnitus will be monitored during weekly assessment visits. Everyone participating in the study will receive the settings we anticipate to be helpful for one period of the study. You will be given a detailed personal schedule of appointments at the end of your first visit after we have confirmed that you are a good candidate for the study.

4. Participation with visits to the lab will always be supervised by one of our lab members. You will be trained on how to use the device by a lab member prior to taking it home. You must agree to use the device exactly as instructed. You will then be asked to operate the device from home for 30-60 minutes per day for 6 weeks at a time. You will be asked to come in for outcome measures every week. Once you have completed the home-use portion of the study, you will be asked to return the device to the study team. If we are unable to contact you to arrange for device return, or you refuse to return the device, the Office of General Council and/or the UM Police department will be notified of device theft, pursuant to Mich. Comp. § 750.356(3), § 750.356a(1), “Felony Theft in Michigan”.
5. As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments, apply your study treatment as directed, and report any adverse reactions you may have during the study.
6. If you should become pregnant during the course of the trial it is your responsibility to contact the study team and let them know of the change as soon as possible.
7. After you have completed the study treatments, we will contact you once a month for 3 months to follow up on how you are doing and to complete the Tinnitus Functional Index.

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

The study will last approximately up to 36 weeks (there is some room for flexibility to accommodate your scheduling needs), with outcome assessment visits to the lab occurring every week for the duration of the study. The outcome visits will take about 3 hours at the most. When you are first provided with the device, we will take additional time in the appointment to make sure you are comfortable and capable of using the device. If necessary, we can schedule additional appointments until you are comfortable with using the device on your own and we are confident in your ability to do so. You will be asked to take the device home and operate it for 30-60 minutes per day. We will also be available to you for additional appointments during the home-use portion of the device if you feel it is needed.

At the end of the study, we will reach out to you by phone once a month for three additional months to check in and see how you are doing.

4.3 When will my participation in the study be over?

Your participation will be complete when you have completed the home testing with the device and completed the follow-up assessments. It will take approximately 36 weeks to complete the study.

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

Your biospecimens and collected information may be shared with the National Institutes of Health, National Institute of Mental Health (NIMH).

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

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

4.5 Am I allowed to share details about the study and my personal experience within the study to the public via Internet, tinnitus support groups, newsletters, etc.?

In a clinical trial there is potential for research participants to draw their own conclusions, based on their subjective experience, that may differ from the bigger picture (ie. biased). In an effort for all participants to be unbiased, we ask that you please refrain from sharing with the public (via Internet, tinnitus support groups, newsletters, etc.) your personal experience using the device and Section 4 of the Informed Consent. This is to ensure our results are valid. If we do find you are sharing this information, you will be asked to leave the study. After participating, we highly encourage you to remain quiet as it may affect the experience, and possibly the results, of participants still enrolled in the study.

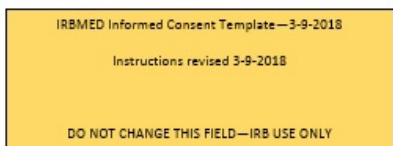
period		Arm 1	End Period 1	Washout	Arm 2	End Period 2	Washout	EOS	Post-study monitoring
visit	Screening	Baseline 1	End of weeks 1-5	End of week 6	End of week 12	End of week 18	End of week 19-23	End of week 24	Weeks 28, 32, 36
day	Day 0	Days 7, 14, 21, 28, 35	Day 42	Days 49- 84	Day 91	Day 133	Days 140- 168	175	252
window		*+ or - 3 days, but 5 days between weekly visits	*+ or - 3 days, but 5 days between weekly visits	*+ or - 3 days, but 5 days between weekly visits	*+ or - 3 days, but 5 days between weekly visits	*+ or - 3 days, but 5 days between weekly visits	*+ or - 3 days, but 5 days between weekly visits	*+ or - 3 days, but 5 days between weekly visits	*+ or - 3 days, but 5 days between weekly visits
Informed Consent	x								
Medical History	x								
Tinnitus Maneuver Checklist	x		x		x			x	
Audiogram	x	x			x			x	
TFI	x	x	x	x	x	x	x	x	x
THI		x	x	x	x	x	x	x	
TinnTester		x	x	x	x	x	x	x	
THS		x	x		x		x	x	
MML		x	x		x		x	x	

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 known or expected risks are:

The device is being custom manufactured for this study. It generates sound and somatosensory stimulation. Risks include hearing a sound that is subjectively too loud or uncomfortable. It also includes feeling the electrical stimulation. While current levels are quite low and we use limitations and safety limits (see below) and therefore we do not expect adverse experience, it is possible that if current levels are too high you might experience tingling or twitching at the site of the electrode pad.



All research has the potential risk of confidentiality breach. The investigators conducting the research have put the following mechanisms in place to protect your confidentiality: all test results coded. Information is also stored in password protected encrypted files or locked in a cabinet accessible only by the investigators. See Section 9 of this document for more information.

As with any research study, there may be additional risks that are unknown or unexpected. While unlikely, it is possible that your tinnitus may become louder or more noticeable during the trial.

The researchers will try to minimize these risks by:

There are software and hardware limiters in place to ensure the device never outputs any unsafe somatosensory or sound stimulation. We will also make individualized adjustments in the lab to ensure both the sound and somatosensory stimulation are also at comfortable levels for you. Because of the limits in place, you will be unable to make unsafe adjustments to the sound and somatosensory stimulation. This study is to test the effectiveness of the device.

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.

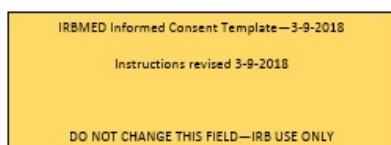
Although the study is double-blinded, we will also have an Independent Safety Monitor (ISM) who helps to monitor the study and report any adverse events. This individual is a clinical research monitor of the Michigan Institute for Clinical & Health Research (MICHHR) who is not directly affiliated with the research project but who has the knowledge and background to monitor the results for worsening of symptoms or side effects. If symptoms worsen or other adverse events reported, then you will discontinue use of the treatment and will be evaluated by a physician on our research team.

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. Because we are measuring the potential effect of a tinnitus treatment, the results would become confounded if you were to participate in another tinnitus treatment.

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

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. You may find that you experience a reduction in your tinnitus by participating in this study.



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

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

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

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

You are not obliged to take part in this or any other study. There are no standard treatments shown to be effective for tinnitus that are currently available. An alternative method of treatment such as sound therapy may be used to treat your condition. Although the research device is available as part of this study, you should check with the researcher and/or your primary care physician to discuss your options including how to obtain any alternative treatments and whether they must be obtained through a physician or require medical supervision.

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" (below).

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

No

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

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

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

A participant will become ineligible to continue in the study if he/she misses more than one visit for each of the following 6-week time periods: Arm 1 treatment, Arm 1 washout, Arm 2 treatment, Arm 2 washout. A participant will be considered lost to follow-up if he or she fails to return for 2 consecutive scheduled visits and is unable to be contacted by the study site staff.

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. If you are not sure what these are, see Section 4.1 above or 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.

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.

Prior to participating in this study, you will undergo a basic medical evaluation by one of the physicians on our study team to make sure you are qualified to participate in the study. Based on the results of the examination, you may be required to undergo further evaluation at UMHS or by your own medical provider prior to participating in the study. This follow-up testing is considered standard clinical practice, and therefore you would be responsible for any associated costs. For example, some people who experience tinnitus also report other symptoms which would require further examination using imaging (Example: MRI) in order to rule out particularly underlying causes or conditions. This referral is consistent with routine clinical care, and follows best-practice guidelines and therefore you would be responsible for these costs.

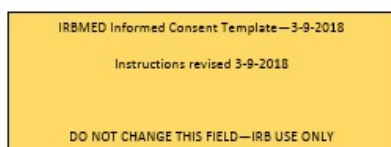
If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

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 will have to arrange for treatment on your own, as the study will not provide medical treatment or provide any compensation to you. You or your insurance provider will be billed for all costs of treatment for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

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

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

You will receive a parking voucher (free parking) for each visit to the lab. You will also receive \$100.00 upon completing the 24 weekly visits.



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

The company whose product is being studied: If the device proves to be effective, in2being, the company making the device, could profit.

The University of Michigan is an owner and Susan Shore and David Martel are named inventors on a patent for the stimulus protocol used in this trial (PATENT NO: 9,682,232 APPLICATION NO: 14/977,416. ISSUE DATE June 20, 2017.) The results and findings of the research have the potential to enhance the optioned intellectual property that is being used in the study. The research has the potential, whether in actuality or in appearance to enhance the value of both the Intellectual Property and the value of the outside organization.

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.

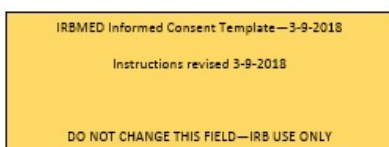
9.1 How will the researchers protect my information?

All of your information will remain confidential and only shared with the investigators of this study. Any findings published or presented at a scientific conference will contain only subject numbers and no names.

If you tell us or we learn something that makes us believe that you or others have been or may be harmed, we may be required to report that information to the appropriate agencies.

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

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing



information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

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

A description of this clinical trial will be available on <http://www.clinicaltrials.gov/>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site 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?

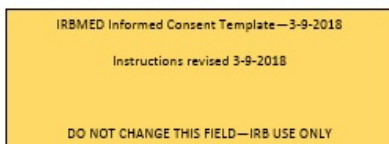
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

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:

- 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 the researchers or others during or after this study. Examples include:

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



- 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 UMHS medical record.
- 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 study team may need to use the information to distribute your compensation.

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

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

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

Examples of reasons for this include:

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

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

9.4 When does my permission to use my PHI expire?

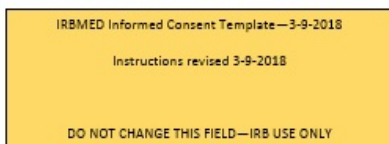
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

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



- Express a concern about the study

Principal Investigator: Susan Shore, Ph. D.
Mailing Address: 1150 W. Medical Center Drive
4605 Med Sci II, Ann Arbor, Mi 48109-5616
Email: sushore@med.umich.edu

Co-Investigator: Kara Leyzac, Ph.D:
Email kleyzac@med.umich.edu

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

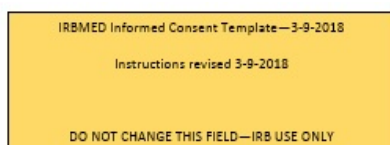
If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111. *When you call or write about a concern, please provide as much information as possible, including the name of the 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/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____.

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-D

Consent/Assent to Collect for Unspecified Future Research

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

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

Print Legal Name: _____

Signature: _____

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

Sig-G

Principal Investigator or Designee

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

Printed Legal Name: _____

Title: _____

Signature: _____

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