

ClinicalTrials.gov Document Cover Page

Official Study Title: IMBUE RETAIN: Transcutaneous Auricular Neurostimulation (tAN) for Patients With Co-occurring Posttraumatic Stress Disorder (PTSD) and Opioid Use Disorder Starting Buprenorphine Therapy

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Document Name: Informed Consent Form

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Principal Investigator: Joel G. Sprunger, PhD, University of Cincinnati College of Medicine

Funding Sponsor: National Institute on Drug Abuse (NIDA)



**UNIVERSITY OF CINCINNATI - MEDICAL
CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

STUDY TITLE:	
Pilot Randomized Clinical Trial of Transcutaneous Auricular Neurostimulation for Patients with Co-occurring PTSD and Opioid Use Disorder Starting Buprenorphine Therapy	
PERFORMANCE SITE: <<Insert site name>>	PROTOCOL PRINCIPAL INVESTIGATOR: Joel Sprunger, PhD
SITE PRINCIPAL INVESTIGATOR NAME: <<Insert site PI name>>	PHONE NUMBER (24-hour Emergency Contact) <<Insert 24-hour contact number>>
PARTICIPANT NAME:	DATE OF BIRTH:

KEY INFORMATION

Purpose of the Study:	This voluntary research study tests transcutaneous auricular neurostimulation (tAN) with the Sparrow Ascent device against placebo to see if it is a useful tool that helps people with PTSD and opioid use disorder (OUD) stay in buprenorphine therapy.
Length of the Study:	Active participation in the study is just over three months and consists of a baseline assessment, 12 consecutive weeks of research visits, and a post-active treatment assessment. Research staff will access the medical record to collect six-month treatment follow-up data.
Risks:	Risks associated with study participation include the possibility that confidentiality may be breached, emotional discomfort from answering questions about difficult life experiences, and discomfort related to device usage. See section titled “What are the Risks and Discomforts of the Research Study?” for additional risks related to the study.



Benefits of the Study:	Study participants may benefit from the extra support that participating in a clinical trial provides. This includes respect and interest from study staff over the course of participation. All participants will have multiple opportunities to talk about difficult life experiences with a trained clinician during the baseline and post-active treatment assessments. Having the opportunity to recount these events at one's own pace with a non-judgmental professional may bring some relief. In addition to naloxone (Narcan) that is available to all ^[Site Name Redacted] patients, study participants will receive additional information about receiving naloxone from other sources, including by mail.
Alternative procedures:	If you choose not to participate in this study, you may receive standard buprenorphine care for opioid use disorder. Participation is voluntary and whether someone decides to participate in the study does not affect their ability to receive care at [Site Name Redacted] .

INTRODUCTION:

Before you agree to participate in this research study, it is important that you be told the purpose, procedures, benefits, risks, discomforts, and precautions of the research. Your participation in this study is entirely voluntary. If you decide to participate, you may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you. Be sure to ask questions while you read this consent document and ask questions if there is anything that you do not understand.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research study is to investigate what effects transcutaneous auricular neurostimulation (tAN), as delivered through the Sparrow Ascent device, has on helping people with co-occurring posttraumatic stress disorder (PTSD) and opioid use disorder (OUD) as they start and continue buprenorphine therapy. The Sparrow Ascent device has been FDA-cleared as effective for reducing the symptoms of opioid withdrawal. Although the device has not yet been approved by the FDA to treat PTSD, research with comparable devices has shown promise for reducing PTSD symptoms. Because the Sparrow Ascent device provides stimulation to two major nerves and influence our “rest and digest” response (specifically, the vagus and trigeminal nerves), it may also relieve PTSD symptoms, especially the long-term “fight, flight, freeze” response that keeps people feeling hyperalert and on-edge.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you are between 18 and 65 years old, you have been diagnosed with OUD and are starting, or have recently started, buprenorphine therapy for OUD. You are also being asked because you have been diagnosed with, or are likely to be diagnosed with, PTSD. Most of the research on effective treatments for OUD, including buprenorphine medication, did not include people who also have PTSD. However, we know that PTSD and OUD symptoms can



make things especially challenging for people trying to start and stay in treatment. For this reason, it is important that we test interventions, like the Sparrow Ascent device, for its ability to help people experiencing both of these conditions at the same time.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study for approximately 14 weeks. The study consists of a baseline assessment, 12 consecutive weeks of research visits, and a post-active treatment assessment. Research staff will access the medical record to collect six-month treatment follow-up data but this will not require any work from you.

You may discontinue use of the device or withdraw from the study at any time. If you decide to stop using the device during the study, we encourage you to talk to the researcher first so that stopping can be done safely. There are currently no known risks with abrupt discontinuation of use of the device. If you discontinue use of the device, the research staff will ask that you return the device and any remaining materials. The research staff may still invite you to complete research visits and assessments. If you choose to withdraw from the study, the research staff will ask that you return the device and any remaining materials. The research staff will not ask you to complete any more study visits. In this case, we will keep the data collected to the point of withdrawal and you may choose whether the research staff continue to collect data from your routine medical care. The research team may decide to take you off this research study at any time. Examples of situations in which the researcher may decide to stop your participation include concerns about safety, such as becoming pregnant during the study or active suicidality.

You may be contacted in the future by representatives of the University of Cincinnati who are interested in asking you survey questions about your participation in this research study. If you choose to participate in the survey, your responses will be used for quality assurance purposes only.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is sponsored by the National Institute on Drug Abuse (NIDA). The study is directed by Joel Sprunger, PhD, the Principal Investigator at the University of Cincinnati.

The local investigator for the study at <<insert local performance site name>> is <<insert name of site investigator>>.

Medical supervision for the study is provided by [Name Redacted].

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About <<number>> people will take part in this study at <<Fill in the name of the local performance site>>. This is the only enrolling site.



WHAT IS INVOLVED IN THE RESEARCH STUDY?

Below is a table showing when study procedures occur and the expected length of time required for each. Please note that the length of time for each appointment will depend on individual differences in things like reading speed and ability to produce a urine sample for drug/pregnancy testing.

Phase	Time Point	Procedure	Expected Visit Length
Eligibility and Randomization	Week 0	Baseline assessment	150 minutes/2.5 hours
	Week 0	Randomization and Sparrow Ascent Training	60 minutes/1 hour
Active Participation	Weeks 1-12	Weekly Research Visits	60 minutes/1 hour
Post Treatment	Week 13	Post-treatment assessment	150 minutes/2.5 hours
Follow-up	6 months	Medical Record Check	N/A

As shown in the chart above, you will complete a baseline assessment to confirm eligibility in the study. This will consist of completing questionnaires that ask about demographic information, history of substance use and mental health treatment, substance use, traumatic life experiences, symptoms of PTSD, quality of life, and other related topics. You will also complete a diagnostic interview with a mental health professional. All participants will be asked to provide a urine sample to test for the presence of buprenorphine and other substances. Participants of childbearing potential will also complete a urine pregnancy test. With this information, the research staff will be able to determine whether you are eligible to continue.

If eligible for the study, our research staff will randomize you to a study condition within 28 calendar days of your buprenorphine induction. Neither you nor the researcher will choose what group you will be in, and you will not know which group it is. You will have an equal chance of being placed in a group that receives the active treatment (tAN) or a placebo, like the flip of a coin.

Once you have been randomized to a group, research staff will train you on how to use the device. Depending on whether you have started buprenorphine already, your training may occur on the same day as your baseline assessment. Otherwise, research staff will work with you to get this appointment scheduled as quickly as possible. During the training, the research staff will describe the required minimum dosage schedule for using the device over the first week (i.e., 2 hours of stimulation per day for 5 days). They will then provide you with the materials you will need for the week (e.g., earpieces, cables, batteries).

After training, you will return to the clinic each week for the active participation phase. At these visits, you will provide a urine sample, answer survey questions about cravings and symptoms, provide feedback about your experience with the device, and receive instruction about the minimum dosage schedule for the next week. You will also receive new materials for the device, as needed. We will contact members of your treatment team, including your buprenorphine prescriber, to perform study activities. These activities include documenting updates on your progress and activities in the buprenorphine program, and getting feedback on any potential influence the study device may have on



your treatment. At the last of these weekly visits, you will return the study device and any remaining materials you have for it.

After 12 weeks with the device, you will complete a post-treatment assessment. At this visit, you will complete nearly all of the measures and interviews from the baseline assessment so that we may see change over time. We will also record an interview with you to hear about your experience with the study device and give us feedback about the study. This is the end of your active participation in the study. Later, we will access your medical record to collect data about your engagement with your treatment program and buprenorphine prescription status at six months following your randomization.

Depending on your availability and the availability of our research staff, some study procedures and assessments may be performed remotely through secure teleconference or telephone calls, if needed. Meeting in person is always preferred, but if this is not possible for an assessment or research visit, we will attempt to conduct study procedures through a secure two-way audiovisual call (e.g., Zoom). If this is not possible, we will attempt to complete study procedures through a phone call with you. In these cases, we may send you a secure hyperlink to your email to complete the study measures online.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

As with any study, participation comes with potential risks that we describe below:

- **Breach of confidentiality:** As with any study, there is a potential risk of loss of confidentiality. To maintain your confidentiality, study records and data will be stored in compliance with the International Conference on Harmonization (ICH) guidelines. Your identity will never be revealed in research reports. We have a federal Certificate of Confidentiality that protects you by making sure that we cannot release sensitive information about you, such as drug use. We will only share data for research purposes that cannot be traced back to you. Audio recordings will be stored securely and transcribed by the research team. These transcriptions will be de-identified so that the text we use for research will not contain any information that can be traced back to you. The audio recordings will never be shared outside of this project and once they have been transcribed, we will delete the audio recordings. When conducting assessments and study procedures remotely, we will use secure methods of communication. We will prioritize the use of two-way audiovisual calls (e.g., Zoom) because we can encrypt them end-to-end, meaning that if someone would somehow intercept data from the call, they would not be able to understand it. If we are unable to use an audiovisual teleconference call, we will attempt a telephone call instead. However, while unlikely, phone calls may be intercepted.
- **Emotional discomfort:** You may feel emotionally upset from answering personal questions. The study will ask you about experiences with traumatic events to confirm a PTSD diagnosis. To help, you may choose to not answer questions that are uncomfortable. A mental health professional will lead the clinical interviews and they are able to help you if you happen to become emotionally upset.



- Sparrow Ascent device: The stimulation that is delivered by the Sparrow Ascent device has been shown to be safe. Most therapy-related side effects are fixed by turning the system off or removing the earpiece. Examples of possible side effects include (from a current, 90-day study):
 - Skin irritation at the earpiece (2 out of 60)
 - Redness where the device is touching the skin (0 out of 60)
 - Tingling, prickling, or numbness (0 out of 60)
 - Red, itchy rash due to allergy (0 out of 60)
 - Temporary pain or discomfort due to stimulation (2 out of 60)
 - Earache (0 out of 60)
 - Muscle twitching during stimulation (0 out of 60)
 - A piece of the device fails resulting in loss of, or reduced, therapeutic effect (3 out of 60)

- Psychiatric destabilization: Although we do not expect the interview to make symptoms worse, it is possible that you may feel emotionally upset. If you become upset, research staff will offer to help you through breathing exercises. If you become emotionally unstable at any point during the study, the research staff will work with your counselor to make sure that you are supported. If this happens, you will stop using the Sparrow Device. We will continue to contact you to check on your safety and provide support each week. When it is time to complete the follow up assessment, we will invite you to participate as long as it is safe for you to do so. We will still access your medical record to collect information about your treatment progress at six months after you started the study.

- Suicidal thoughts and/or plans: It is possible that you may have suicidal thoughts and/or plans while participating. If this happens, research staff will ask you about the nature of these thoughts, whether there is a plan for suicide, access to means to carry out the plan, and if you intend to carry it out. If you tell us that you intend to carry out a plan to die by suicide, research staff will collaborate with you on a safety plan and notify your counselor. We will work together to help you get to a higher level of care right away. If this occurs during the baseline assessment, your participation will stop. If this occurs during active participation, your use of the Sparrow Ascent device will stop. We will continue to contact you weekly to check on your safety and provide support, as appropriate. When it is time for the post-active treatment assessment, we will invite you to complete it if it is safe for you to do so. We would still access your medical record to collect follow up data about your treatment progress at six months after you started the study.

- Opioid overdose and death: The early parts of recovery from OUD are a risky time for opioid overdose and death. One reason is that tolerance is usually lower because of the time spent taking medications for OUD, like buprenorphine, instead of using. Another reason is that someone may use more of a substance than they usually would because the medications for OUD may reduce the effect. [Site Name Redacted] provides all patients with a naloxone kit at their intake



appointment and more kits as needed. We provide our participants with information about receiving additional naloxone kits by other sources, including by mail, through the getmonaloxone.com program.

There may be unknown or unforeseen risks associated with study participation.

WHAT ARE THE REPRODUCTION RISKS?

Although the tAN treatment being investigated in this project has a well-established safety profile and has FDA-clearance for use with infants experiencing opioid withdrawal symptoms, the effects on a fetus are unknown. Out of an abundance of caution, you should not become pregnant while in this research study. Additionally, should not nurse your baby while participating in the active treatment phase of this research study. You must notify the researcher right away if you become pregnant. You should discuss birth control options with your researcher.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

You may benefit from the extra support that participating in a clinical trial provides. This includes respect and interest from study staff over the course of participation. You will have multiple opportunities to talk about difficult life experiences you have had with a trained clinician during the baseline and post-active treatment assessments. Having the opportunity to recount these events at one's own pace with a non-judgmental professional may bring some relief. In addition to naloxone (Narcan) that is available to all ^[Site Name Redacted] patients, you will receive additional information about receiving naloxone from other sources, including by mail.

We also hope the information learned from this study will benefit other patients with PTSD and OUD in the future.

WHAT IS THE CLINICAL TRIALS REGISTRY?

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 results. You can search this Website at any time.

WHAT IS A CERTIFICATE OF CONFIDENTIALITY?

To further protect your privacy, the researchers have been issued a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the researchers may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.



A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Even with the Certificate of Confidentiality, if the investigator learns about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, they will report that to the proper authorities. If keeping information private would immediately put you or someone else in danger, the researchers would release information to protect you or another person.

AVAILABILITY OF INFORMATION

You will receive a copy of this signed and dated consent form.

You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

You will receive diagnostic feedback on the results of the clinical interviews. You will not receive individual research results.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

There are no costs to you for participating in this study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will be paid \$50 per assessment (i.e., baseline and post active treatment) and \$30 per weekly research visit. This means that you may be reimbursed up to \$460 for your participation in the study. You will be paid for each of these activities that you complete.

<<Participants must be informed how (e.g., check, cash, gift certificate, etc) and when (e.g., on-site at each visit, by mail at each visit, etc.) payment will be provided. Insert site specific details here.>> (If you withdraw from the study before the day 90 visit, you will not be eligible for the day 90 visit payment.)

If you receive payments for being a part of this research study, you will be asked to complete an Internal Revenue Service (IRS) form (i.e., a W-9). << Insert site specific details here, if applicable.>>

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

If you become ill or injured from participating in this research study, (local site) will decide on a case-by-case basis whether to reimburse you for your out-of-pocket health care expenses.

[Insert local compensation language if applicable]



If you think that you have been hurt by taking part in this research, call [Name of site PI] at [local PI 24-hour phone number], as soon as possible. If needed, you will be referred for emergency medical care. If the injury is a direct result of a study-related procedure, the cost of emergency medical care will be paid by [the local site] only if it is not paid by your health insurance, a government program, or other third party. The Sponsor has no plans to pay for medical care for any other injury whether or not it might be related to taking part in this research.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

The investigators will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you have questions about the study, you will have a chance to talk to one of the study staff. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

Nothing in this consent form waives any legal rights you may have, nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

HOW WILL THIS RESEARCH STUDY AFFECT YOUR LEGAL STATUS?

Being in this study or refusing to be in this study will have no effect on your court case, probation, or parole. You will NOT get in trouble for refusing. You will NOT get special privileges if you agree.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Every effort will be made to maintain the confidentiality of your medical and research records related to this study. Agents of the University of Cincinnati, the National Institute on Drug Abuse and <<insert name of local performance site>>, including the monitor, the auditor, the Institutional Review Board (IRB), and other regulatory authority(ies) will be granted direct access to your original medical and research records for verification of clinical trial (research study) procedures or study data without violating your confidentiality, to the extent permitted by the applicable laws and regulations. By signing this consent form, you or your legally authorized representative are authorizing such access. De-identified study data may be published; however, you will not be identified by name. Your identity will remain confidential unless disclosure is required by law.

Authorization to Use and Disclose Health Information

<<This section may replace a stand-alone HIPAA authorization document. This section or a standalone HIPAA authorization is required for all research being performed at a Covered Entity allowing Protected



Health Information (PHI) to be shared for purposes specified in the Authorization. [Site specific HIPAA language may be entered here.](#) California sites must update the font size to 14 for HIPAA authorization if using this template language. >>

A federal regulation known as the Privacy Rule requires that the researchers get your written permission to use your health care information in this research study. If you sign this form, you are giving your authorization for the use and disclosure of your health information for research purposes. You do not have to give this authorization. If you do not give your authorization, you cannot be in the research study. However, if you are being treated as a patient at [Site Name Redacted] or another agency, you will still be able to receive care.

Who Will Use and Disclose My Health Information? The researchers will use your health information to conduct, review, and determine the results of the study. The researchers may also use your information to prepare reports or publications about the study. Your name will not appear in any report or publication without your permission.

Who Will Receive My Health Information? The following people or groups may receive your health information:

- Researchers who are conducting this study at other study centers
- The study sponsor or its representatives, including companies it hires to provide study-related services
- University of Cincinnati Institutional Review Board (IRB) or an outside external IRB reviewing the study
- Other compliance committees responsible for overseeing the research
- Federal and State agencies, such as the U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), and other US and non-US government bodies that oversee or review research

Will My Information be Protected by the Privacy Rule After it is Disclosed to Others?

If the groups above share your health information with others, it will no longer be protected by the Privacy Rule.

Will My Authorization Ever Expire? Your authorization will not expire.

May I Take Back My Authorization? You may take back your authorization at any time by writing to the Site Principal Investigator, <<insert site PI name>>. If you take back your authorization, you will not be able to stay in this study. If you take back your authorization, the study team will not collect any new health information about you. Information that has already been collected may still be used and given to others. If you withdraw your authorization, no new health information will be collected unless you have a side effect related to the study.

May I Look at My Study Information? You will be provided with diagnostic feedback based on the mental health clinical interviews. However, the data collected in this study will not become a part of your medical record. Therefore, you will not be able to examine or make copies of these data when the



study is complete.

Information that could identify you will be removed from the study data so that your responses cannot be traced back to you. After removal, the study data could be used for future research studies. The study data could also be given to another researcher for future research studies. This may be done without getting additional permission from you.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

If you have questions, concerns, complaints and/or suggestions about this research study or to report a research-related injury, please contact the Site Principal Investigator <<insert site PI name>> at <<insert 24 hour contact number>> or the Principal Investigator Dr. Sprunger at [Contact Information Redacted].

Please call the University of Cincinnati Institutional Review Board at 513-558-5259 (Monday – Friday 8 am to 5 pm) if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.
- Have questions, concerns, complaints and/or suggestions about the research.
- Cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

Comprehension Tool

- | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|-------|
| 1. My participation in this research study is entirely voluntary. | True | False |
| 2. If I am eligible after screening, I will be randomized to receive either the active tAN treatment or placebo. | True | False |
| 3. As part of my participation, the researchers will need to access my medical record to collect information about my treatment as a client in my buprenorphine therapy program, including my medications and services that I receive. | True | False |
| 4. If I choose to participate, I will actively participate for approximately 14 weeks, with a baseline assessment, 12 weekly research visits, and a post-treatment assessment. | True | False |
| 5. I may choose to stop participating in the study at any point without it affecting my ability to continue as a client of my treatment agency or receive services in their buprenorphine therapy program. | True | False |



**UNIVERSITY OF CINCINNATI - MEDICAL
CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

STUDY TITLE: Pilot Randomized Clinical Trial of Transcutaneous Auricular Neurostimulation for Patients with Co-occurring PTSD and Opioid Use Disorder Starting Buprenorphine Therapy	
PERFORMANCE SITE: <<Insert site name>>	PROTOCOL PRINCIPAL INVESTIGATOR: Joel Sprunger, PhD
SITE PRINCIPAL INVESTIGATOR NAME: <<Insert site PI name>>	PHONE NUMBER (24-hour Emergency Contact) <<Insert 24-hour contact number>>
PARTICIPANT NAME:	DATE OF BIRTH:

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. If I do not participate or if I discontinue my participation, I will not lose any benefits or any legal rights. My participation in this research is completely voluntary. I have received (or will receive) a copy of this signed and dated form for my records and future reference. I have been given the information about the use and disclosure of my health information for this research study.

I give my consent to participate.

I authorize the release of information concerning treatment relating to psychiatric conditions, alcohol use disorder, and substance use disorders, including opioid use disorder, to the parties listed in the authorization section of this consent for the purposes described above.

 Participant

 Date

PERSON OBTAINING CONSENT

I have read this form to the participant and/or the participant has read this form. An explanation of the research was given and questions from the participant were solicited and answered to the participant's satisfaction. In my judgment, the participant has demonstrated comprehension of the information.

 Signature and Title of Person Obtaining
Consent and Identification of Role in the Study

 Date