

SOUNDHEAL RESEARCH PARTICIPANT CONSENT FORM

TITLE: Effectiveness of the SoundHeal (Heal) Multi-Sensory Integrative Therapy in Enhancing Emotional Regulation Among Justice-Involved Youth and its Effect on Therapeutic Alliance and Mental Health Outcomes

PROTOCOL NO.: SHSLOSJC001
WCG IRB Protocol #20254416

SPONSOR: SoundHeal, Inc.

INVESTIGATOR: Nishat Bhuiyan, PhD
3444 Fairfax Drive
Arlington, Virginia 22201
United States

**STUDY-RELATED
PHONE NUMBER(S):** 408-230-9070

SLO county Juvenile Hall providers are generally available during regular county business hours, which are 8am - 5pm, except during county holidays. I understand that some programs have different hours of availability. For non-urgent matters after-hours, I understand I or my child can leave messages in the provider's confidential voicemail.

480-406-2644

**SUB-
INVESTIGATOR(S):** Nicco Reggente

SOUNDHEAL CONSENT SUMMARY

In this consent form "you" generally refers to the research participant. If you are being asked as the parent or guardian to permit the participant to take part in the research, "you" in the rest of this form generally means the research participant.

You are being asked for your consent to take part in a research. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

Your participation in this research is voluntary. You may decide not to participate, or you may leave the research at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

Your choice about joining or not joining will have no effect on your probation, parole, case outcome, or release decisions. Parole boards and probation staff will not be told whether you take part.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

How long will I be in this research?

We expect that your taking part in this research will last for eight (8) weeks.

Why is this research being done?

The purpose of this research is to try out a treatment program offered in SLO County Juvenile Hall called “Heal.” This program is open to all SLO County Juvenile Hall youth. This treatment program uses the investigational device called Healpod, a physical space where you sit to experience music, sound, light, and gentle vibrations. The goal of these sessions is to help you manage how you feel, be more involved in your treatment, feel calmer, and find healthier ways to handle stress.

What will I do if I agree to take part in this research?

If you decide to participate in this research, the general procedures include sitting in the Healpod, a safe space about 4 feet wide and 6 feet tall with a curtain for privacy. While inside, you will listen to music, sounds, and gentle vibrations for about 5 minutes. This session will happen every time just before you meet your therapist over a period of 8 weeks. After each session, you will be asked short questions and will write in a journal or draw pictures about how you felt.

Could being in this research hurt me?

Possible minor risks include feeling restless, or emotional. Some people might find the vibrations or lights mildly uncomfortable. You can stop immediately at any time. Staff and therapists are nearby and available to support you during and after each session. All handwritten journals will be stored in a lockbox with only your Juvenile Hall therapist having access to them for your safety. Digitized versions of the journals will be shared with the research team. Use of personized UserID’s will ensure that none of your personal information will be identifiable.

Are there any benefits to participating in this research?

If the treatment works, you may feel calmer, more relaxed, and better able to handle stress. These sessions may help you integrate better with staff and peers at Juvenile Hall, improve communication, emotional awareness, and treatment outcomes, and make it easier to talk with your therapist. What we learn could help create better support for other young people in the future.

What other choices do I have besides taking part in this research?

If you choose not to participate in this research, you will still receive all the regular services and support already provided at Juvenile Hall. This includes counseling with therapists, group activities, school programs, and any medical or mental health care you normally receive.

What else should I know about this research?

Being in this research is your choice. Saying yes or no will not affect your legal rights, or probation, case, at the SLO County Juvenile Hall. Your information will be kept private, and your name will not be used in any reports. There is no cost to you and no payment to you for

being in the research. You will still receive all your regular counseling and care if you choose not to join.

This research does NOT involve the collection of identifiable biospecimens, such as blood or urine samples.

DETAILED RESEARCH CONSENT

You are being invited to take part in a research. A person who takes part in a research is called a research participant.

In this consent form “you” generally refers to the research participant. If you are being asked as the legally authorized representative, parent, or guardian to permit the participant to take part in the research, “you” in the rest of this form generally means the research participant.

Why is this research being done?

The purpose of this research is to learn whether the Heal intervention can help SLO County Juvenile Hall youths better manage their emotions, have deeper conversations with their therapist, and build coping skills. Youths in the juvenile justice system often face high levels of trauma, anxiety, and emotional struggles. Traditional therapy in detention can be difficult because many youths find it hard to open up to their therapist right away.

The Heal intervention is a supportive tool. It uses a booth called the Healpod that is about 4 feet wide and 6 feet tall where participants can sit comfortably for around 5 minutes and experience calming sounds, music, and gentle vibrations in a softly lit space. Afterwards, participants write or draw in a journal about how they feel. The goal is to help youth calm down, feel more in control, and integrate better with staff and peers at, improving communication, emotional awareness and treatment outcomes.

Currently, this treatment program has already been available to clients in the SLO County Behavioral Health and other mental health and addiction recovery facilities around California and Oregon for the past five years. The Healpod has received positive feedback on its use in supporting emotional regulation, being more engagement in treatment, improving positive mental health outcomes related to anxiety, stress and depression, and helping individuals build coping skills for the long term to lead successful lives outside of those facilities.

All participants of the SLO County Juvenile Health program will be offered the opportunity to participate in this proposed research.

How long will I be in this research?

We expect that your participation in this research will last 8 weeks.

What happens to me if I agree to take part in this research?

If you choose to take part in this research, here is what will happen:

- **Listen to sounds, music, and gentle vibrations:** You will sit inside the Healpod, a small, private booth with a curtain. Inside the Healpod, you will listen to calming music and sounds, feel gentle vibrations through the chair, and experience soothing light. Each session lasts around 5 minutes.
- **Participate for 8 weeks:** You will take part in Healpod sessions as often as you see your therapist weekly (1-2 times), for a total of 8 weeks.

- While inside the Healpod, you will sit in a comfortable padded chair and listen to calming music, sounds, and gentle vibrations. The Healpod will have soothing lights. You are free to stop the session and restart another one or leave at any time, even in the middle of your session, by opening the curtain and walking out.
- **Journaling:** After each session, you will be asked to fill out a journal about how you felt before, during, and after the session. If writing is hard, you can draw.
- **Questions/surveys:** At the start, during, and at the end of the 8 weeks, you will answer a set of questions about your mood, emotions, and ability to cope. Most questions are simple check-box or scale questions (for example: “When you are upset do you feel overwhelmed?”).
- **Meet with your therapist:** After your Healpod session, you will meet with your therapist. You can read from your journal to share how you felt.
- **Therapist will answer questions about you:** These questions are similar to the questions you will answer about yourself. They will report how the therapist felt about your engagement in the session.
- **Support while being in the Healpod:** Staff and therapists will be nearby. You will always get your regular counseling and care at SLO County Juvenile Hall.

What are my responsibilities if I take part in this research?

If you decide to be in this research, here is what you will be asked to do:

- **Take part in around 5 minute Healpod sessions** as many times as you meet the therapist each week for 8 weeks. Each session lasts around 5 minutes.
- **Try to relax in the Healpod** while music, sounds, lights, and gentle vibrations play. You will actively listen, but you are free to stop the session by opening the curtain and walking out of the Healpod, if you want.
- **Write or draw in a journal** after each session to show how you felt before, during, and after the session. If writing is difficult, you may draw or ask clinical staff for help with prompts.
- **Answer survey questions** at the beginning, middle, and end of the research (weeks 0, 2, 4, 6, and 8) about your mood, emotions, feelings, anxiety, stress, depression and coping. Most questions are short, check-box style questions. Other questions require you to write what you experience and how you feel. You can get assistance from your therapist in case you need to understand the questions to make sure you answer them to the best of your ability.
- **Meet with your therapist** after Healpod sessions as part of your regular care. You will share your journal with your therapist and answer a set of questions the therapist will ask you about your Healpod experience.
- **Stop at any time** if you feel uncomfortable, upset, or simply want to restart a session or stop.

Could being in this research hurt me?

The most important risks or discomforts you may expect from taking part in this research are:

- You may feel restless, or emotional while sitting in the Healpod.
- Some people may feel mild sleepiness from the relaxation or feel a surge of strong feelings come up during journaling.
- The gentle vibrations may feel uncomfortable for a small number of participants.

- There is the risk of a loss of confidentiality of your research-related information.
- There may be risks or side effects which are unknown at this time.

These risks are small because:

- Sessions are very short (~5 minutes).
- The Healpod is safe, non-invasive, and you can stop at any time.
- Juvenile Hall Staff will always be close by to help if you feel uncomfortable.
- Since there is only a soft curtain, you are free to walk out of the Healpod, or someone can open the curtain easily from the outside.
- You will never be left alone without support.

Will it cost me money to take part in this research?

No. It will not cost you or your family any money to be in this research. All Healpod sessions, journals, and surveys are provided as part of the research.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. However, others who have used the Healpod have reported the following benefits:

- Feeling calmer and more relaxed after the session in the Healpod
- Learning healthier ways to handle stress by journaling and/or drawing
- Being more open to talk with therapists
- Want a better quality of life outside of the Juvenile justice system
- Making conversations with therapists easier and getting more out of the therapy sessions

Possible benefits to others include:

- Helping staff and researchers learn whether the Healpod is a good tool for supporting youth in Juvenile Hall.
- Improved programs may be created in the future that may help other young people manage their feelings, cope with stress, and participate more fully in therapy.

What other choices do I have besides taking part in this research?

If you choose not to be in this research, you will still receive all of the usual care and services at Juvenile Hall. Whether you agree to participate or not, you will continue to receive your regular counseling with therapists, school programs, group activities, medical care, and other support services provided.

Not being in this research will not change your access to other services in any way.

What happens to the information collected for this research?

The information you provide in this research includes your questionnaire answers, therapist assessments, and journals. Your name and personal details will not be used in any reports. Your answers to questions will not be shared with anyone besides your therapists and the research team at County Juvenile Hall, not even in court.

All journals will be scanned and stored on secure servers. Only approved Juvenile Hall clinical staff, authorized people listed below, and the Heal research team will have access to the scanned

journals and questionnaires. When results are shared, they will be combined with information from other participants so that you cannot be individually identified.

Your private information and your medical record may be shared with individuals and organizations that conduct or watch over this research, including:

- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research

What we learn may be used to create reports, presentations, or publications about the research. These reports will describe group results, not individual stories, and your identity will always be kept private and secure.

Who can answer my questions about this research?

If you have questions about the research or about taking part, you can ask:

- **On-site probation or clinical staff**
- **Principal Investigator (PI):**
Nishat Bhuiyan, Phone: 480-406-2644
- 408.230.9070

SLO county Juvenile Hall providers are generally available during regular county business hours, which are 8am - 5pm, except during county holidays. I understand that some programs have different hours of availability. For non-urgent matters after-hours, I understand I or my child can leave messages in the provider's confidential voicemail.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. Your parent/guardian may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

The Healpod is designed to be safe, and no injuries are expected. However, on-site staff and therapists will be nearby to help you right away as needed.

You will still receive all regular medical care provided at Juvenile Hall. The research team is not offering special payment or extra medical treatment if you are injured from being in this research. No other payment is routinely available from SLO County, the Principal Investigator, therapist, or sponsor.

If you think you have been injured because of the research, you should let your probation officer and/or on-site therapist know immediately.

Can I be removed from this research without my approval?

Yes. You may be taken out of the research even if you want to stay in. This could happen if:

- The clinical and or probation staff believes it is no longer safe for you to continue.
- You do not follow through with the research activities (like not being consistent in using the Healpod, refusing Healpod sessions, or refusing to fill out the questionnaires).
- The Juvenile Hall program decides to stop the research or if your stay at the facility ends before the research is finished.

If you are removed from the research, you will still receive all of your regular care and services at Juvenile Hall. Being taken out of the research will not affect your legal rights, probation status, case outcomes, or parole decisions.

What happens if I agree to be in this research, but I change my mind later?

Being in this research is your choice. You can stop at any time, even if you already said yes. If you choose to stop, it will not change the care, counseling, services, legal rights, or probation decisions you normally receive at Juvenile Hall.

If you decide to leave the research, the information collected from you up to that point, such as surveys or journals you already completed, will still be used for research, but no new information will be collected.

If you want to stop being in the research, tell the probation officer or your therapist.

Will I be paid for taking part in this research?

You will not be paid for taking part in this research. The results from this study may lead to new commercial products or tests. If this happens you will not receive any compensation.

STATEMENT OF CONSENT

- All children are required to assent
- If assent is obtained, have the person obtaining assent document assent on the consent form

This Consent Form covers the participation of a juvenile currently incarcerated at the SLO County Juvenile Hall. The minor is too young to give binding legal consent, so the appropriate parent/guardian will sign this Consent Form.

Signature of Parent/Guardian

Date

Signature of Person Obtaining Consent

Date

Signature of Impartial Witness (where applicable)

Date

I confirm that I have fully understood the research and agree to participate.

Name of Minor Giving Assent

Date

I have explained the study to the participant and the participant has orally agreed.

Signature of Person Obtaining Assent

Date

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?

The study doctor and the study staff. They may also share the research information with an agent for the study doctor, if applicable.

Who might get this information?

The sponsor of this research. “Sponsor” means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information may be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

Authorization:

I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

Signature of Participant/Parent/Guardian

Date

Relationship of Parent/Guardian