## STUDY INFORMATION:

**Study Title:** Extended home-use trial of a novel device to reduce chronic pain

**Principal Investigator (Head Researcher):** David Putrino, PT, Ph. D.

**Physical Address:** Mount Sinai Hospital; Abilities Research Center (ARC) 5 E 98th St, Sub-basement, room 18.

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**Phone:** 212-824-8369

## SUMMARY OF THIS RESEARCH STUDY:

A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is to assess the effectiveness of a new wearable device at relieving chronic pain. The device is called the Sana Pain Reliever (Sana PR – pictured below). The Sana PR is a mask with ear buds that will display light in front of your eyes. The device runs for 16 minutes at a time. The device is not FDA approved.

If you choose to participate, you will be asked to:

- Follow study directions for the entire 14-week duration of the study.
- Attend all four video calls or study visits to the Abilities Research Center at Mount Sinai.
- Complete the procedures outlined in Description of What's Involved section

The main risks to you if you choose to participate in this study are associated with photosensitivity to the flashing lights, which can include headaches, dizziness, and nausea.

Participating in this research may not benefit you. Others may not benefit from this study either. A possible benefit to you may be a reduction in your chronic pain.

If you are interested in learning more about this study, please continue to read below.

## PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you experience long lasting pain.

Funds for conducting this research are provided by Mount Sinai.

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 website will include a summary of the results. You can search this website at any time.

## LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last 14 weeks. The number of people expected to take part in this research study is 160.

## DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

This study will be an at home trial with the Sana Pain Reliever device (Sana PR). For this trial, you will be loaned the device and a tablet, with the application that controls the device and has electronic forms of the questionnaires, for 8 weeks. You will be instructed on how to use the device and application, and you will also be given all equipment necessary to charge the Sana PR headset and tablet device. The study will include four video calls or study visits to the Abilities Research Center located at: 5 E 98th St.,

Sub-basement room #18, New York, NY, 10029. The following outlines what is involved at each stage of the study:

**Study Devices**

The mask and computer tablet will be loaned to you for the duration of the study. If you will complete the study visits over video call the devices will be mailed to you ahead of the first call. The tablet will come with a video calling software (Zoom) installed for completing these study video calls. You will then mail the devices back to us using a provided shipping label. If you will complete the study visits in person the devices will be given to you at these study visits, and you will return the devices to us at later study visits (described below). Both devices will be activated and deactivated remotely at the start and end of the study.

**Clinical Assessment 1 (Start of Study)**

During this video call/visit, you will complete a short screening to make sure this study is a good fit for you based on your type of pain. You will be asked to complete several questionnaires about your pain, sleep quality and your quality of life. You will also be asked to report demographic information, a medical history of your pain (including techniques you use to try to help relieve the pain) and your current medications (both prescribed and over-the-counter). You will be loaned the study tablet at this visit and taught how to use it. This visit will last approximately 90 minutes.

**At Home Symptom Monitoring (Weeks 1–2)**

For the two weeks between Clinical Assessment 1 and Clinical Assessment 2, you will use this tablet once a day immediately prior to going to sleep and answer a few questions in the application about your quality of sleep from the night before, pain levels and the medication you used that day. Reach out to the research team at (212) 824-8369 if you have any questions or issues with the tablet or application. During this time, your level of compliance to the protocol will be monitored. Your eligibility to continue participating in the next at home portion of this study with the Sana PR device is dependent on your ability to comply with what is being asked of you to complete during this At Home Symptom Monitoring period.

**Clinical Assessment 2 (End of Week 2)**

During this video call/visit, you will be asked to complete several questionnaires about your pain, sleep quality and your quality of life. You will also be asked to report any changes in your current medications (both prescribed and over-the-counter) and techniques you use to manage your pain from the first initial assessment. Then you will be randomized into one of two study groups that will test two different settings of the Sana PR device. The study group you will be assigned to will be chosen by chance, like flipping a coin. You will have an equal chance of being given each study group. Neither you nor the study researcher will choose or know which study treatment you are getting. This information could be obtained in an emergency, however. You will then be taught how to use the Sana PR device, and will then complete your first session using the device. The video call/visit will last approximately 90 minutes. A member of the research team will call you 48 hours later to check to see if you have had any negative symptoms as a consequence of participating in this study that result in immediate and/or long-term negative health outcomes from using the device or participating in this study. The researcher will also check for difficulties using the devices and answer any questions you may have.

**At Home Use of Device (Weeks 3-10)**

You will control the Sana PR device with the same application on the tablet that you used in the first two weeks of the study. Over this time, you will use the Sana PR device whenever you are in pain. Before and after each use, the application will ask you to rank how much pain you are feeling. Before your first daily use of the device, you will also be asked to rank your quality of sleep from the evening prior. In addition to using the device during the day, you will also use the device each night immediately prior to or accompanying to falling asleep. Each night, prior to using the device, the application will ask you to rank your pain and will ask which of your reported medications you took that day. Additionally, every other week the application will ask you to complete a few questionnaires about your pain, quality of sleep and quality of life. You will be notified via text message on your mobile device and by a notification on the tablet about these questionnaires. Reach out to the research team at (212) 824-8369 to report any negative symptoms or experiences from using the device or if you have any questions or issues with the Sana PR device, tablet or application. During this time, your level of compliance to the protocol will be monitored. The research team will reach out to you via telephone or email if the level of your compliance drops to make sure you have not stopped using the device due to a negative health outcome from using the device.

**Follow-Up 1 (End of Week 10)**

During this video call/visit, you will be asked to complete several questionnaires about your pain, sleep quality, your quality of life and how you felt the device impacted you, if in any way. You will also be asked to report any changes in your current medications (both prescribed and over-the-counter) and any changes in the techniques you use to manage your pain. . You will also be asked to report your thoughts on the device and if you would use it in your daily life. Additionally, you will be asked to report any negative symptoms or experiences from using the device. This video call/visit will last approximately 90 minutes.

**At Home Symptom Monitoring (Weeks 11–14)**

For the four weeks between Follow-Up 1 and Follow-Up 2, you will use the study tablet once a day immediately prior to going to sleep, and answer a few questions in the application about your quality of sleep from the night before, pain levels and the medication you used that day. Reach out to the research team at (212) 824-8369 to report any negative symptoms or experiences from using the device or if you have any questions or issues with the tablet or application.

**Follow-Up 2 (End of Study)**

During this video/call visit, you will be asked to complete several questionnaires about your pain, sleep quality, your quality of life and how the device impacted you, if in any way. You will also be asked to report any changes in your current medications (both prescribed and over-the-counter) and any changes in the techniques you use to manage your pain. You will also be asked to report your thoughts on the device and if you would use the device in your daily life. Additionally, you will be asked to report any negative symptoms or experiences from using the device. This video call/visit will last approximately 90 minutes.

Because this project involves the use of a medical device, it is necessary that we make a note of your participation in the electronic medical record. That way anyone treating you will be aware of your

participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown.

## USE OF YOUR DATA AND/OR SPECIMENS:

In the future, your identifiable information may be removed from the private information that is collected as part of this research. After this removal, the information could be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information. That means that a research project might be done that you would not consent to if provided with the details of that research project.

## YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things:

- You must report any changes in medications and any changes to your current strategies for dealing with your pain within 28 days of beginning this study or for the duration of this study.
- Reporting all negative symptoms or experiences from using the device.
- Contacting the research team immediately if there are technical difficulties with the device.
- Completing the procedures outline in Description of What's Involved section.

*Returning the mask and tablet devices loaned to you for this study.*

## COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you a maximal total of $150 for your time and effort. This amount will be pro-rated: you will receive $25 for each of the two baseline assessments, and $50 for each of the two follow-up assessments, which amounts to $150. This will be paid to you in the form of a check following your final assessment. Checks require some time to be prepared and will be given to you as available. Payment is dependent on you returning both the Sana PR and tablet devices.

## POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be a reduction in the amount of chronic pain that you typically experience.

## REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

- Standard risks associated photosensitivity: nausea, headache, dizziness
- In addition to these risks, because this is an investigational device that is not FDA approved, there are risks that may not be known and the severity of these risks may not be known. The unknown risks might be minor or might be major (death).

## OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

Instead of being in this research study, you may choose one or more of the many currently available treatments for chronic pain. These choices include:

- Pharmaceuticals such as antidepressants, anticonvulsants, local anesthetics, and opioids.
- Physical techniques such as cognitive behavioral therapy, relaxation/mindfulness, physical therapy, chiropractic therapy, TENS, and thermal applications.
- Surgical options such as Botox nerve blocks, trigger point injections, and epidural steroid injections.

Potential risks and benefits of these alternatives include:

- Pharmaceuticals can have adverse side effects and, in some cases, there is a risk of addiction.
- Surgical options are invasive and carry general risks associated with minor surgical procedures such as infection or risk of nerve damage.
- These alternatives may result in pain relief

The study staff are unable to prescribe any of the above alternative treatment options in any circumstance. You should consult your personal physicians if you would like to consider any of these options.

Your participation in the study does not preclude you from using these alternate options, however, should you wish to commence a new treatment modality we ask that you do inform us of your intentions to change your pain management as promptly as possible.

## IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

## ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff. At that point, the research team will ask that you return the equipment that was loaned to you back to the research team.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the investigator can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. Data stored as part of the research study can also be destroyed without your consent. More possible reasons for removal from the study include experiencing an adverse event from using the device, you begin a new treatment for your neuropathic pain over the course of the study, you experience a musculoskeletal injury or develop an eye or ear infection over the course of the trial. Additionally, your compliance to the protocol will be monitored for, and lack of compliance to the study protocol may lead to the investigator withdrawing you from the study according to the discretion of the PI or research team.

## CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator at phone number (212) 824-8369.

If you experience an emergency during your participation in this research, contact 911 or go to the emergency room.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.

- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

## DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

The researchers in this study have no financial conflicts of interest to disclose.

## MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your: name, address, telephone/fax numbers, dates directly related to the individual (birth, date of diagnosis), e-mail/internet protocol (IP) addresses or web universal resource locators (URL's), social security number, medical records number.

The researchers will also get information from your medical record about your diagnosis, medical history and history of what treatments you have tried for your pain.

During the study the researchers will gather information by:

- taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study

will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- The commercial sponsor and/or their representative (who will use the results for submissions to the Food and Drug Administration): Sana Health Inc
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Food and Drug Administration
- The United States Department of Health and Human Services and the Office of Human Research Protection.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this

access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information? Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?
NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

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**Notice Concerning HIV-Related Information**

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

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**ADULT PARTICIPANT:**
Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Signature of subject | Printed Name of Subject | Date | Time |

**PERSON EXPLAINING STUDY AND OBTAINING CONSENT:**

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Signature of consent delegate | Printed Name of consent delegate | Date | Time |

**WITNESS SECTION:**
*When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).*

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Signature of Witness | Printed Name of Witness | Date | Time |