Standardized Hypnotic Susceptibility Testing to Facilitate Development of a Machine Learning Tool to Characterize Physiological Biomarkers of Calm and Tranced States
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NCT07102810
Document Date: 7/15/2025

STUDY INFORMATION:

Study Title: Standardized Hypnotic Susceptibility Testing to Facilitate Development of a Machine Learning Tool to Characterize Physiological Biomarkers of Calm and Tranced States
Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital
Lead Researcher (Principal Investigator): David L. Reich, MD
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SUMMARY OF THIS RESEARCH STUDY:

This form tells you about a research study you may want to join. Taking part in this study is your choice. You do not have to join. If you say no, it will not affect the care you get at Mount Sinai. You should only agree to join if you understand the study and all your questions are answered. If you join, we will tell you if we learn anything new that might change your mind.

This study will collect data about your body during a hypnosis session. Hypnosis is a known method that can help people lower stress and fear. We will measure brainwaves, heart rate, breathing, skin moisture, and record video of your movements. This data will be used to train and develop an artificial intelligence model to learn how calm or anxious someone is.
If you decide to join, you will:

- Have one 3-hour study visit at Mount Sinai.
- Take part in a hypnosis session while wearing sensors and being recorded.
- Answer questions about your anxiety before and after the session.
- Get a follow-up phone call 2-14 days later.

The risks are small. You might feel a bit uncomfortable from the sensors. Hypnosis may cause a mild headache, dizziness, tiredness, or brief emotional stress. There is also a small risk that your data could be shared by mistake, but we will take steps to protect your privacy.

You will not get any direct benefit from joining, but your help could improve tools that track anxiety and alertness in the future. If you are interested, please keep reading.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you are a healthy person.
Your participation in this research study is expected to last approximately 3 days, including one study visit that will be about 3 hours long and one follow-up phone call 2 days after the study visit.

There are 50 people expected to take part in this research study at Mount Sinai Hospital.

Funds for conducting this research study 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 website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:

- You will come to Mount Sinai Hospital for a 3-hour study visit. At the visit:
  - The study team will confirm eligibility
  - You will fill out a brief questionnaire about your anxiety
  - We will place sensors on your head and body. A set of 21 gel-covered sensors will be placed by a trained technician on your scalp and will be held in place with netting. A sensor will be placed on your chest to measure breathing and heart rate. A sensor will be placed on your finger to measure the moisture level of the skin. We will then measure your responses over a period of approximately 15 minutes with your eyes closed.
  - You will take part in a hypnosis session led by a trained hypnotist. The session will last about one hour. Hypnosis is a natural state where you feel very relaxed and focused, and you may be more open to suggestions. In this research study, you will follow a 90-minute standard hypnosis process. It will include guided imagery, relaxation exercises, and suggestions to help improve your focus, comfort, or cause specific physical responses, like moving your arm. You will stay aware and in control the whole time and can stop the session whenever you want. The researchers will collect information during your session to help create a future device that can measure anxiety and awareness levels. During the session, both the hypnotist and research team will be in the room. They will collect data on your brainwaves, heart rate, breathing, and skin moisture.
  - Video of your face and body will be recorded during the session. Audio will also be recorded. These recordings will be used to help develop an artificial intelligence (AI) model. This AI model is a computer system trained to recognize patterns in data – such as changes in facial expressions, speech, or physiological signals – to estimate a person's level of relaxation or anxiety. Your recordings and physiological data will be used to train this model to better understand how people experience hypnotic states.
  - There is a small risk of loss of privacy from the collection of video and audio recordings. However, strict security measures are in place to protect your data, including restricted access to data storage systems and the removal of identifying information before analysis. Only the study team will have access to the raw recordings.
  - After the session, you'll fill out the same anxiety questionnaire again
- 2 days after the visit, you will receive a follow-up phone call to check on how you are doing.

Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information and/or study data might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____ No_____

If "Yes", please indicate your preferred method of contact: (initial all that apply)

[ ] Email [ ] Phone [ ] Letter [ ] Text

USE OF YOUR DATA:

The research team will never use or share your personal information (such as, name, address, date of birth) and/or study data that are collected as part of this study for future research, even if your identity is removed. Your data will only be used to complete this study and then will be destroyed.

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:

- Attend your scheduled study visit.
- Follow instructions during the session.
- Complete the anxiety questionnaires before and after your hypnosis session.
- Inform the team of any discomfort.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this study, you will be paid $100 for your time and effort. You will be given a gift card at the end of study visit.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this happens if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due. It is possible that products may someday be developed with the help of your data, and there are no plans to share any profits from such products with you.

POSSIBLE BENEFITS:

This study is not designed to benefit you personally. However, your involvement may contribute to future tools that help reduce anxiety without medication.

POSSIBLE RISKS AND DISCOMFORTS:

- The risks of hypnosis are very low. Most people find it relaxing and enjoyable. But like any kind of mental or emotional treatment, a few people might have mild side effects. These can include feeling a little emotional, sleepy, or more sensitive to suggestions. In rare cases, hypnosis might bring up old memories or unexpected feelings. You can stop the session at any time if you feel uncomfortable. Trained staff will be there to help if you have any concerns.
- Mild skin irritation or discomfort from the wearable sensors.
- Emotional discomfort or anxiety during or after the study visit.
- Risk of loss of private information; this risk always exists but there are procedures in place to minimize this risk.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that being in this research study has harmed you, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted. If you decide to stop being in the study, please contact the Lead Researcher or the research staff.

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must contact the study team using the information on the first page. Even if you withdraw your permission, the Lead Researcher 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 taking part in the research study.

Withdrawal without your consent: The Lead Researcher or Mount Sinai 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 research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number 929-596-7950.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information collected for this study.

What PHI is collected and used in this research study, and might also be shared with others?
As part of this study, the research team will collect your name, date of birth, telephone number, and e-mail address.

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Collecting vital signs that generally include readings of blood pressure, heart rate, breathing rate, and temperature.
- Video will be collected and stored/analyzed in secure environments.
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are.

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, 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 Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).

In all disclosures outside of Mount Sinai, you will not be identified by name, 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 Lead Researcher 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 (IRB) 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, *OHRP,* 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. The results of this research may be published. However, your name and other identifying information will be kept confidential.

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

Will you be able to access your records?
If you receive your care at the Mount Sinai Health System, you will continue to have access to your medical records, but the research information collected in this study will not be part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, 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?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the contact information on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this 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 taking part in the research study.

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, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

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) 416-0197. These agencies are responsible for protecting your rights.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) 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 participant.
- You want to get information or provide input about this research.

ADULT PARTICIPANT:

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

Signature of Participant	Printed Name of Participant	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time